CLINICAL INVESTIGATION PROGRAM REPORT

DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FT GORDON, GA 30905

FY 95

REPORT DOCUMENTATION PAGE

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Kent M. Plowman, M.D., PhD
Colonel, Medical Corps
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Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

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Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1995, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff.
A Detail sheet of each protocol giving the objective, technical approach, and program is presented.

14. SUBJECT TERMS

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279

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G	- Grant	**TA**	- Task
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CLINICAL INVESTIGATION

PROGRAM REPORT

01 OCTOBER 95

CONTROL SYMBOL: RCS MED-300 (R)

Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

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The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

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The cover this year features a baroque painting by the pseudonymous Cesare Ripa who bases it on the description of a lost work by the Greek artist, Zeuxis. The topic is pain, particularly chronic pain, in a gout-ridden man (Podagricus). The symbol for pain is the darkly clothed man in the foreground holding a recently extinguished, smoking candle. The spent candle is meant to symbolize man's spirit which can be snuffed out by pain or suffering. It emits some warmth for a time before becoming cold permanently as in the final pain of death. This smoldering quality of pain bespeaks of its transitional nature.

The *fatto* or event depicted is of a man with gout affecting his right foot, classical podagra. He has a fly whisk to chase away any insects which might add to his torment. He has summoned the physician, Hippocrates, depicted with the staff of Aesculapius in his left hand. In his right, he offers his advice consisting of the single word "Patience" as his prescription. Since patience or fortitude is considered one of the four cardinal virtues delineated by Aristotle, it sums up the need for the patient to practice this virtue. The basis of gout was widely believed to be associated with intemperance in food and drink. Hence, temperance and prudence would also be implied. The fourth virtue, justice, could be suggested by the need to obey the laws of nature as manifested in his own body. All of the virtues were generally considered linked. One could not be thought virtuous without some balance in all aspects of one's life. This patient seems to be turning away from the physician's advice, preferring his current pain. Both recognize that time is required for change to occur. It is the state of the inner disposition which is in doubt--the choice between patience and mere endurance.

The responsibility of physicians to relieve suffering dates from antiquity. This symptom is one of the key factors responsible for patients seeking help from a physician. Despite the responsibility to relieve pain and suffering often, it is rarely the focus of physician education, research, or practice. Suffering includes physical pain (nociception) but is not limited to it. It most often involves some complex threat to the personhood of the patient and its attendant fears. It is thus intensely personal and often not shared unless a bond is built into the physician-patient relationship that permits the level of trust necessary for this most private of revelations. The respect for the patient's personhood is a fundamental tenet of medicine even when the physician does not share the patient's belief system. It becomes necessary to create at least a hypothetical space for the dimensions of that value system.

The ideal patient-physician interaction would need to address four or five inter-related dimensions. The first (biological or physiological) is usually handled well and is the focus of most medical training. The second (psychological) includes both intellectual and emotional features to include that person's memory of his or her own history. That memory will be affected by some of the other higher dimensions to be addressed. In general medicine does adequately most often with at least part of this dimension. The third (ethical) involves a personal moral compass of right and wrong (conscience) which pertains to core beliefs and their link through natural law, society, and cultural history. These begin to become more complex for a physician in a society with nonhomogeneous ethnic and cultural histories to deal with in patients who differ in backgrounds. Little formal training is given to develop a sensitivity to this dimension. The fourth (spiritual) involves immaterial dimensions of experience and belief. Each person has one even if not of an overtly religious nature. It includes the nature of one's relationship to others and to creation, of one's philosophy of existence and its meaning, and of one's life experiences in esthetic qualities. Here the problems of interaction become exceedingly complex. The physician has the responsibility at a minimum to respect this dimension in patients even though not understood or shared. Creating a hypothetical space for this level of interaction is analogous to a regard for art. One may not be able to see the beauty in a given work; but one still has the responsibility to appreciate the esthetic sense of others whose insights open up a sense of wonder, awe and beauty towards the object. A possible fifth (relational) is, in one sense, a component of all of the others.

Suffering involves a loss or threat to some one or more dimensions of one's personhood. It is intensely personal and involves a threat to some disintegration of self. The physical pain of a kidney stone, to someone who has had it before and knows clearly what it is, may not include much suffering unless some other features are present that evoke fears. The pain of a normal childbirth may produce joy to such a degree that the woman is unconcerned with the nociceptive sensations. On the other hand, her relationship to the child's father, her family and cultural values, and her most personal hopes and aspirations may add other complexities to her experience.

Consider a hypothetical forty year old man who had retired from the military two years ago after having served as an aircraft technician in the Persian Gulf during the Iraqi conflict. He has developed chronic headaches, subjective memory loss, easy fatigue, joint pains in one knee and both shoulders, and recurrent diarrhea with intermittent right upper quadrant abdominal pain. He has been fired from his civilian job for poor performance which he attributes to his symptoms and inability to concentrate. He is thoroughly evaluated to include neuro-psychological testing, infectious disease batteries, radiographs, colonoscopy, and extensive blood work. He is diagnosed as having migraine headaches, degenerative joint disease, and irritable bowel syndrome, but no definitive psychiatric diagnoses. No objective memory loss is documented, but he meets the criteria for chronic fatigue syndrome. His wife is especially anxious to find out what is wrong and keeps calling to see what new tests can be done.

He and his family suffer at several dimensions in this model. He has many defined, but only partially treatable, chronic conditions which produce overt pain. At the psychological level he has his basic temperament which influences much of what he perceives through certain modalities. He is influenced by his education, his emotional development, and his memory of his history. This includes his military service in the Persian Gulf to which it is popular to attribute various nondescript groupings of symptoms which fit established diagnostic criteria poorly. These symptoms seem to flourish in the murky limits of how some of these conditions interact with the person and in the questions about the specific chemicals or toxins which might have been involved. Many similar symptoms can be seen in contemporaries who did not see Persian Gulf service or in Vietnam era veterans who have attributed their symptoms to herbicide exposure. Clearly the trauma of actual warfare with its dangers, horrors, and uncertainties can precipitate various emotional states depending on the personality structure of the pre-exposure disposition.

The ethical dimension of the patient is not readily apparent in the example being used. However, conscious motives to use means which one believes to be at least questionable to achieve an end thought to be just would add such a factor into the complex calculus. Even without conscious malingering, a person may truly be convinced that something dreadful is happening and he is caught up in it. This may be further shaped by publicity and by interacting with others who report similar symptoms to include some he had not thought about before. In a litigious society with a strong rights emphasis, the suggestion of added emphasis and dramatic portrayals of victimhood may seem to be legitimate approaches. A person with more of an inner oriented temperament inclined toward self-reliance might consciously avoid any overstatement of symptoms and might even down play them to health professionals. His sense of the ethical along with his understanding of his own personal responsibility would have more of a tendency to accept problems as part of aging and of assumed risks from life.

The spiritual dimension becomes even more complex to treat. One's whole concept of the existence of a spiritual reality beyond the material and of the nature of that reality will color many attitudes and reactions. An agnostic materialist might become angry that these events have occurred but is powerless to change them in any meaningful way. This could lead to bitterness unless a more focused object for the anger is found. It could lead to a form of stoicism and self-discipline that only he could change matters in any meaningful way. A person with a religious

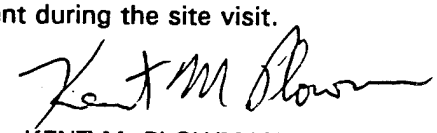
approach might take several different attitudes, ranging from self-pity or anger that it was happening to him to acceptance of suffering as a means to transform his life into a more sublime model.

The inter-relational dimensions vary immensely. The person who is ordinarily the principal bread winner for the family might become unemployable for various reasons and force other members to assume this role. That person might assume some sort of invalid status and become dependent, thereby fundamentally altering his relationship to his family. Another would find great courage and resoluteness through the struggle and bring new vitality to the family. The interactions with the other family members would have mutually important consequences in terms of growth as persons with character whatever choices are made.

These dimensions would influence greatly some of the ways that the same set of medical conditions would present in a patient. They would also affect both how the brain would interpret for the mind the nature of nociceptive impulses. The concept of pain in even its simplest form would be greatly modified. The aspect of suffering in its more immaterial sense would vary even more. For some people an existential crisis might occur and others would through various sublimation methods be able to grow and mature into finer human beings.

The assorted subtleties in the personhood of various patients with similar diagnoses makes research on complex diseases daunting. For this reason, research often concentrates on the biologic dimension with simply a smattering of the psychological dimension. However, a great richness abounds in how certain diseases exhibit themselves in a particular population of patients, even when a common etiologic factor such as an infectious agent is involved. The presentation may be different, the symptom complex may vary, the course of the illness might not be the same, and the impact on the person's work and life may be a function of these other dimensions as well. The information could be highly important. The means of acquiring it is daunting. Most research projects do not even collect such "soft" data. Serious scientists do not concern themselves with the art of medicine and its disorderly data.

Ordinary orderly ordinal data collection continues apace at EAMC despite some big changes. The Department of Clinical Investigation has had major turnovers within the past year with some of the new members of the senior research team still arriving over the next few months. We are planning for a move from our WWII wooden contonement buildings to some newer and more permanent structures over the coming fiscal year. The big news is that we received AAALAC accreditation based on our site visit this summer. This seemed an impossibility for us in our facility with its severe limitations. Very special thanks are in order to CPT Kim Vlach, VC and her laboratory animal service. They have worked extraordinarily hard to bring this off. LTC Ron Banks, VC contributed immensely to our effort with assistance visits. He offered invaluable counsel and even came back from civilian life to be present during the site visit.



KENT M. PLOWMAN, PhD, MD
Colonel, Medical Corps
Chief, Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1995

A. Objective:

The objective of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach:

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing:

Name	Rank	MOS	Title
Plowman, Kent M.	COL	61F00	Chief
Runyan, Dennis	COL	63F	Chief, Biometrics and Statistical Design
Craft, David	MAJ	71A67	Immunologist/Microbiologist
Vlach, Kim	CPT	64A00	Veterinarian
Czerwinski, Steven	CPT	71B67	Biochemist
Figueroa, Ronald J.	SSG	91K30	NCOIC
Mason, Chana L.	SGT	91K20	Med Lab NCO
Collins, Demetrius D.	SPC	91T10	Veterinary Technician
Naylor, Timothy L.	SPC	91K10	Med Lab Specialist
Horner, Jack A.	GM13	01301	Asst C, Res Histologist
McPherson, James C. III	GS13	01320	Biochemist, PhD
Runner, Royce	GS11	00644	Medical Technologist
Best, Norma	GS9	00644	Medical Technologist
Chaung, Augustine, H. PhD	GS9	00644	Medical Technologist (MRDC Grant)
Ferguson, Phyllis	GS6	00303	Protocol Coordinator
Silas, Mary Ann	GS5	00303	Asst Protocol Coordinator
Nelson, Manuela	GS5	00404	Biological Lab Tech
Reisenger, Rebecca	GS4	00312	Clerk-Steno
Reid, Tilda	WG2	00404	Biological Lab Tech

Officer: 3 authorized; 5 required; 5 assigned
Enlisted: 5 authorized; 9 required; 4 assigned
Civilian: 7 authorized; 13 required; 10 assigned

One third-party FACT physician assistant in Clinical Investigation.
One third-party FACT medical research assistant in Clinical Investigation.
One third-party FACT clinical data coordinator in Clinical Investigation.
One third-party FACT clinical research assistant in Clinical Investigation.
One third-party FACT clinical research nurse in Clinical Investigation.
One third-party FACT secretary in Pharmacy.
One third-party FACT study site facilitator/clinical research nurse in Clinical Investigation.

d. Funding:

TYPE	Fiscal Year 94	Fiscal Year 95
Civilian personnel to include benefits	358,100.00	379,611.35
Consumable supplies	145,200.00	120,783.08
Civilian contracts to include consultants	11,600.00	11,912.00
TDY	3,400.00	5,081.53
Publications	699.25	875.04
Paper Presentations		17,667.35
CEEP	378,425.00	28,000.00
MEDCASE	413,149.14	-0-
Equipment		90,512.79
Military	450,494.00	365,354.00
Total	1,310,263.39	1,019,797.14

GRANT FUNDING:

1. "Efficacy of Clinical Case Management in the Military" $163,526.00

2. "Risk Reduction Strategies for Pre-Menopausal Military African-American (25-45) Women with CHD or Associated Risk Factors"

CRADA FUNDING:

A Comparison of Two Impression Techniques for Accuracy of Occlusal Contacts
FY 95: $2,042.68.

E. Progress:

Protocol Disposition FY 95

	Completed	Terminated	Ongoing to FY 95
FY 85	1		
FY 87			1
FY 89			1
FY 90	5		6
FY 91	5		5
FY 92	13	1	10
FY 93	14	2	18
FY 94	36	1	16
FY 95	21		24
TOTAL	95	4	81

Number of resident and fellowship programs: 6 Residencies & 1 Fellowship
Number of programs using Clinical Investigation: 5
Number of residents and fellows on approved protocols: 21
Number of approved protocols held by this group: 33

Other training programs that use Clinical Investigation: Graduate students, transitional interns, Psychology interns, Nurse Anesthetist, Radiology, Pathology Health Care Administrators, Oral Maxillofacial Surgery, Peridontal, Prosthodontics, Endodontics:
1 Psychology Intern Program (4 interns)
1 Oral Maxillofacial Surgery Intern Program (4 interns)
1 Peridontic Intern Program (10 interns)
1 Endodontic Intern Program (7 interns)
1 Prosthodontic Intern Program (5 interns)
Number of approved protocols held by this group: 8

Number of hospital staff members on approved protocols: 60
Number of approved protocols held by this group: 62

RESEARCH AWARDS

Recipients of

The Thirteenth Annual DDEAMC Resident Research Award

was

Major John Kragh, MC

for his paper

Parachuting Injuries Among Army Rangers: A Prospective Survey of an Elite Airborne Battalion

The paper was presented at the Eisenhower Army Medical Center Annual Resident Research Presentation Day, May 1995.

Recipient of

The Ninth Annual Dental Resident Research Award

was

Major Thomas J. Butts

for his paper

The Effects of Transforming Growth Factor-Beta and Platelet-Derived Growth Factor on Human Gingival Fibroblasts Grown in Serum Containing and Serum-Free Media."

The paper was based on Protocol 93-12.

INSTITUTIONAL REVIEW COMMITTEE

Clinical Investigation and Human Use Members

Chief, Department of Clinical Investigation, Chairman
Chief, Department of Medicine
Chief, Department of Surgery
Chief, Pharmacy Service
Research Director, Dental Activity
Chief, Department of Ministry and Pastoral Care
Chief, Nursing Education and Staff Development
Chief, Department of Pathology
Signal Center Representative, Fort Gordon, Georgia
Research Director, Department of Family Practice
Reserach Director, Department of Psychiatry and Neurology
Veterinarian, Department of Clinical Investigation
Medical Center Judge Advocate
Chief, Nuclear Medicine Service
Radiation Safety Officer
Chief, Medical Records Administration Section

Animal Care and Use Members

Chief, Department of Clinical Investigation, Chairman
Chief, Department of Medicine
Chief, Department of Surgery
Veterinarian, Department of Clinical Investigation
Signal Center Representative, Fort Gordon, Georgia

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EMERGENCY MEDICINE

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DEPARTMENT OF NURSING

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SOUTHWEST ONCOLOGY GROUP

USA MEDDAC, FORT RUCKER, ALABAMA

USA MEDDAC, FORT STEWART, GEORGIA

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Code:

O - Ongoing
C - Completed
T - Terminated
W - Withdrawn
P - Published
PR - Presented

PUBLICATIONS FY 95

DEPARTMENT OF CLINICAL INVESTIGATION

Sano H, Takatsu T, Ciucchi B, Horner JA, Matthews WG, and Pashley DH: Nanoleakage: Leakage within the Hybrid Layer. Operative Dentistry, 1995, 20(1), 18-25.

Farnsworth WJ, Chuang AH, McPherson JC III, Runner RR, and McPherson JC Jr: Optimization of the Survival of Red Blood Cells Exposed to Fluoride Ion. Eighth Annual Charles R. Ross Research Poster Session Publication of Abstracts, Page 65, Abstract Number 97, 1994.

Cagle TJ, Meyers CE III, Stephens CE, Stroebel GG, McPherson JC Jr, and McPherson JC III: Synthesis and Properties of Fluorophore-Labelled Poloxamer Detergents. 1995 AAAS Annual Meeting and Science Innovation Exposition, Unity in Diversity, Poster Session Abstracts, Page 119, 1995.

Smith TM, Stevens JM, Stroebel GG, Chuang AH, Runner RR, McPherson JC III, and McPherson JC Jr: Poloxamers and Fluorescein-labeled Poloxamers Have Equal Protective Effect on Red Blood Cells Subjected to Shear Stress. 1995 AAAS Annual Meeting and Science Innovation Exposition, Unity in Diversity, Poster Session Abstracts, Pages 152-153, 1995.

Stevens JM, Smith TM, Stroebel GG, Chuang AH, Runner RR, McPherson JC III, and McPherson JC Jr: Application of the Protein Copper-Bicinchoninic Acid Method of Quantitation of Water Soluble Poloxamers. 1995 AAAS Annual Meeting and Science Innovation Exposition, Unity in Diversity, Poster Session Abstracts, Page 146, 1995.

McPherson JC Jr, Chuang AH, Tobias SW, Williams LE, Runner RR, and McPherson JC III: Red Blood Cell Deformability During the Alimentary Lipemia Following Canola Oil and Lard. 1995 AAAS Annual Meeting and Science Innovation Exposition, Unity in Diversity, Poster Session Abstracts, Page 144, 1995.

Naylor TL, Chuang AH, Runner RR, McPherson JC III, and McPherson JC Jr: Fluoride Is More Toxic to Red Cells in Acidic Solutiuon. Georgia J Sci., 53, 50, 1995.

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FASEB J., 9, A365, 1995.

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Sano H, Yoshiyama M, Ebisu S, Nishida H, Horiguchi S, Inokoshi S, Yamada T, Takatsu T, Burrow MF, Ciucchi B, Bouillaguet S, Horner JA, Carvalho RM, and Pashley DH: SEM and TEM Study of Nanoleakage Pathway at the Adhesive Interface. Jap J Conserv Dent 37(6): 1686-1693, 1994.

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Carvalho RM, Yoshiyama M, Horner JA, and Pashley DH: The Interface Between Light-Cured GIC and Acid-Etched Dentin. J Dent Res 74(Spec Iss):17, #46, 1995.

Basquill PJ, Steflik DE, Brennan WA, Horner J, and Vandyke TE: Evaluation of the Effects of Diagnostic Radiation on Titanium Dental Implant Osseointegration in the Micropig. Journal of Periodontology 65:9.

Breault LG, Schuster GS, Billman MA, Hanson BS, Kudryk, Pashley DH, Runner RR, and McPherson JC: The Effects of Intracanal Medicaments, Fillers, and Sealers on the Attachment of Human Gingival Fibroblasts to an Exposed Dentin Surface Free of a Smear Layer. Journal of Periodontology 66:7 (Jul 1995)

Breault LG, Schuster GS, Billman MA, Hanson BS, Krydryk VL, Pashley DH, Runner RR, and McPherson JC: The Effects of Intracanal Medicaments, Fillers, and Sealers on the Attachment of Human Gingival Fibroblasts to an Exposed Dentin Surface Free of a Smear Layer. Journal of Periodontology 66:545-551, July 1995.

DENTAL ACTIVITY

Breault LG, Schuster GS, Billman MA, Hanson BS, Kudryk, Pashley DH, Runner RR, and McPherson JC: The Effects of Intracanal Medicaments, Fillers, and Sealers on the Attachment of Human Gingival Fibroblasts to an Exposed Dentin Surface Free of a Smear Layer. Journal of Periodontology 66:7 (Jul 1995)

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Schmitt JK, Adrian ED, Gardner FM and Gaston ML: A Comparison of Impression Techniques for the CeraOne Abutment; Journal of Prosthodontics 3(3):145-8, 1994 Sep.

DEPARTMENT OF FAMILY PRACTICE

Johnson NA, et al, : Wildervanck's Syndrome Presenting as Hemiparesthesia. Military Medicine April 1995; 160:208-211.

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PRESENTATIONS FY 95

DEPARTMENT OF CLINICAL INVESTIGATION

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Farnsworth WJ, Chuang AH, McPherson JC III, Runner RR, and McPherson JC Jr: Optimization of the Survival of Red Blood Cells Exposed to Fluoride Ion, Eighth Annual Charles R. Ross Research Poster Session, State University of New York, Health Science Center, Syracuse, New York, 07-08 December 1994.

Cagle TJ, Meyers CE III, Stephen CE, Stroebel GG, McPherson JC Jr, and McPherson JC III: Synthesis and Properties of Fluorophore-Labelled Poloxamer Detergents, 1995 American Association for the Advancement of Science, Atlanta, Georgia,
16-21 February 1995.

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Yoshiyama M, Carvalho RM, Sano H, Horner JA, Brewer DP, and Pashley DH: Adhesive Mechanism of Resins to Human Root Dentin, AADR Meeting, San Antonio, Texas, 09 March 1995.

McPherson JC Jr, Tobias SW, Williams LE, Chuang AH, and McPherson JC III: Red Blood Cell Deformability Following Propylene Glycol Feeding in Rats, Federation of American Societies for Experimental Biology, Atlanta, Georgia, 09-13 April 1995.

McPherson JC Jr, Chuang AH, Tobias SW, Williams LE, Runner RR, and McPherson JC III; Red Blood Cell Deformability During the Alimentary Lipemia Following Canola Oil and Lard, 1995 American Association for the Advancement of Science, Atlanta, Georgia,
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Naylor TL, Chuang AH, Runner RR, McPherson JC III, and McPherson JC Jr: Fluoride is More Toxic to Red Cells in Acidic Solution, 72nd Annual Meeting of the Georgia Academy of Science, Augusta, Georgia, 28-29 April 1995.

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Cagle TJ, McCrosson A, Meyers CE III, Stroebel GG, McPherson JC Jr, and McPherson JC III: Fluorescent Polyether Derivatives: Synthesis Purification and Spectral Properties, 72nd Annual Meeting of the Georgia Academy of Science, Augusta, Georgia,
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Paustian PW, McPherson JC III, Chuang AH, and McPherson JC Jr: Comparison of Poloxamers 188 and 407 Treatment on Burn Wound Healing, Society of Academic Emergency Medicine, San Antonio, Texas, 21-24 May 1995.

Craft DW: Clinical Use of Bone Allografts in periodontics and Orthopaedics, Part I. The 19th Annual Meeting American Association of Tissue Banks, Atlanta, Georgia 9-13 September 1995.

Runyan D: Use of the Vitradyne. The 19th Annual Meeting, American Association of Tissue Banks, Atlanta, Georgia, 9-13 September 1995.

McPherson JC III: In-Vivo and In-Vitro Methods of Wound Healing. The 19th Annual Meeting, American Association of Tissue Banks, Atlanta, Georgia, 9-13 September 1995.

Runner R: Strained Tissue Cultures. The 19th Annual Meeting, American Association of Tissue Banks, Atlanta, Georgia, 9-13 September 1995.

Craft DW: Murine Osteoblast Culture Techniques. The 19th Annual Meeting, American Association of Tissue Banks, Atlanta, Georgia 9-13 September 1995.

Craft DW: Clinical Use of Bone Allografts in Periodontics and Orthopaedics, Part II, Use of the KT-2000 and Microextensometers. The 19th Annual Meeting American Association of Tissue Banks, Atlanta, Georgia, 9-13 September 1995.

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DENTAL ACTIVITY

Hanson BS, Best NH, Small BW, and Craft DW: Production and Detection of Endotoxin Stimulated Interleukin-6 (IL-6) in Murine Bone Cell Culture, 95th General Meeting, Washington, DC, May 1995.

Hanson B: Clinical Use of Bone Allografts in periodontics and Orthopaedics, Part I. The 19th Annual Meeting American Association of Tissue Banks, Atlanta, Georgia 9-13 September 1995.

Runyan D: Use of the Vitradyne. The 19th Annual Meeting, American Association of Tissue Banks, Atlanta, Georgia, 9-13 September 1995.

Muse JM: Implants for Irradiated Patients. A Review of the Literature and Clinical Reports, Ninth Annual Resident Research Presentation, US Army Dental Activity, Fort Gordon, Georgia, 02 June 1995.

Rosenheimer RL: The Effect of Thread Removal on the Yield Strength of Osseointegrated Implants, Ninth Annual Resident Research Presentation, US Army Dental Activity, Fort Gordon, Georgia, 02 June 1995.

Berry KA: Nickel-Titanium Versus Stainless Steel Finger Spreaders in Curved Canals, Ninth Annual Resident Research Presentation, US Army Dental Activity, Fort Gordon, Georgia, 02 June 1995.

Ford MW: Assessing the Wear and Cutting Efficiency of Nickel-Titanium Engine Driven Files; Ninth Annual Resident Research Presentation, US Army Dental Activity, Fort Gordon, Georgia, 02 June 1995.

Johnson MA: Cleaning Endodontic Files: Bioburden/Comparison of Ultrasonic Cleaners, Ninth Annual Resident Research Presentation, US Army Dental Activity, Fort Gordon, Georgia, 02 June 1995.

Butts T: The Effects of Transforming Growth Factor-Beta and Platelet-Derived Growth Factor on Human Gingival Fibroblasts Grown in Serum Containing and Serum-Free Medium, Ninth Annual Resident Research Presentation, US Army Dental Activity, Fort Gordon, Georgia, 02 June 1995.

Tolson GE: Effects of TGF-Beta and a Methycellulose Carrier on Incisional Wound Healing, Ninth Annual Resident Research Presentation, US Army Dental Activity, Fort Gordon, Georgia, 02 June 1995.

Fowler EB: Evaluation of Pluronic Polyols on Regeneration in Rat Calvaria, 81st Annual Meeting of the American Academy of Periodontology, District 8 Scientific Forum, 19 September 1995.

Snyder HB: The Mechanism of Nicotine Suppression of Fibroblast Integrin Expression in Vitro, 81st Annual Meeting of the American Academy of Periodontology, District 8 Scientific Forum, 19 September 1995.

Snyder HB: The Mechanism of Nicotine Suppression of Fibroblast Integrin Expression in Invitro, Southern Academy of Periodontology, Billy M. Pennel Graduate Research Competition, 1 July 1995.

Bruce WF: Binding Characteristics of Gallium of Dentin, in Vitro, 81st Annual Meeting of the American Academy of Periodontology, district 8 Scientific Forum, 19 September 1995.

DEPARTMENT OF FAMILY PRACTICE

Epperly TD: What's New with CVA's/TIA's, 1995 Capital Conference: A Family Practice Board Review, Camp Springs, Maryland, 21-26 May 1995.

Epperly TD: The 20th Annual USAFP National Meeting, San Diego, California, 10-14 April 1995.

Epperly TD: Persian Gulf Illness, XXth Annual Scientific Assembly, Uniformed Services Academy of Family Physicians, San Diego, California, 11 April 1995.

Epperly TD: Prostate Diseases. An Update. XXth Annual Scientific Assembly, Uniformed Services Academy of Family Physicians, San Diego, California, 11 April 1995.

Jerant AF: "Persistent Open Anterior Fontanele in a Healthy 32 Month Old Male - Case Report" presented at Uniformed Services Academy of Family Physicians (USAFP) 20th Annual Scientific Assembly, April 1995.

Phelps KS: " The Role of Higher Order Thinking in the Diagnostic Process" Presented at USAFP 20th Annual Scientific Assembly, April 1995, 2nd prize, staff poster.

Farr III JF: "Esophageal Duplication Cyst in a Child Presenting as a Common Cold, presented at USAFP 20th Annual Scientific Assembly, April 1995; 2nd prize, resident poster.

Degaetano J: Persistent Open Anterior Fontanelle in a Healthy 32 Month Old Male. Case report and literature review, presented at the USAFP Scientific Assembly, San Diego, CA April 1995. Awarded AAFP Resident Research Project of the Year for DFCM and DDEAMC.

DEPARTMENT OF MEDICINE

Bauer W: Eosinophilic Pneumonia with Respiratory Failure After Exposure to Diesel Smoke, 76th Annual Session of American College of Physicians, Atlanta, Georgia, 16-19 March 1995.

Whitlock WL, Thompson JL, Doers, J, Honeycutt W, and Hammerschlag, MR: Incidence of Chlamydia pneumonia Infection in Patients Presenting with Acute Bronchitis and Pneumonia with Response to Azithromycin, 1995 American Thoracic Society International Conference, Seattle, Washington, 20-24 May 1995.

Nelson M, Whitlock W: Efficacy of Levofloxacin in the Treatment of Hospitalized Patients with Respiratory Tract Infections. Annual American College of Physicians Meeting. October 1995. (Associate's Competition)

Hancock LD: The Effect of Propylthiouracil on Subsequent Radioactive Iodine Therapy in Graves Disease, 12th Annual ACP/Army Regional Meeting, Reston, Virginia, 18-22 October 1995.

Coleman TA: External Hematuria in a 60 Year Old Man, 5th Annual Georgia Chapter of the ACP Meeting, Lake Lanier, Georgia, 05-06 May 1995.

Lee DF: Pleural Effusion Following Chest Trauma, 5th Annual Georgia Chapter of the ACP Meeting, Lake Lanier, Georgia, 05-06 May 1995.

Mataosky MA: Paralysis and Tachycardia in a Young Filipino Male, 5th Annual Georgia Chapter of the ACP Meeting, Lake Lanier, Georgia, 05-06 May 1995.

Williams P, Whitlock W: All That Wheezes Is Not Asthma, 5th Annual Georgia Chapter of the ACP Meeting, Lake Lanier, Georgia, 05-06 May 1995.

Pisel GA: Induction of the Heat Shock Response Protects Cultured Human Renal Proximal Tubular (HRPT) Cells from Cyclosporine A (CYA) Toxicity. The Washington Capitol Area National Kidney Foundation, Washington, DC, June 1995

Igartua R: Deployment of a Field Dialysis Unit, presented at the Army ACP Meeting, Reston, Virginia, 19 October 1995.

DEPARTMENT OF NURSING

Andrews ML: Women's Health Services-Meeting the Reproductive and Gynecologic Health Needs of Women and Adolescents, 23rd National Institute and Conference of the National Black Nurses Association, 03-05 August 1995.

Hardy MD: Incorporating Nursing Research Into Practice. Keynote Presentation, Annual Nursing Research Day, Fort Rucker, Alabama, October 1994.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

McClure MJ: Teaching Residents to Teach and Supervise, Annual Meeting of Association for Academic Psychiatry, San Antonio, Texas, 01-04 March 1995.

Scheffer R, Correnti EE, and Mukherjee S: History of Premorbid Functioning and Its Deterioration in First-Episode Psychotic Patients, International Congress on Schizophrenia Research, Warm Springs, Virginia, 08-12 April 1995.

Mahadik SP, Murherjee S, Correnti EE, Mahadik JS, and Scheffer R: Mitogenic Response to Basic Fibroblast Growth Factor (bFGF) in Cultured Skin Fibroblasts from First-Episode Psychosis Patients, International Congress on Schizophrenia Research, Warm Spring, Virginia, 08-12 April 1995.

Mukherjee S, Scheffer R, Correnti EE, and Mahadik JS: Early Relapse After Recovery from a First-Episode of Psychosis: Possible Role of Oxidative Stress, International Congress on Schizophrenia Research, Warm Springs, Virginia, 08-12 April 1995.

Mahadik SP, Mukherjee S, Correnti EE, and Scheffer R: Elevated Levels of Membrane Lipid Peroxidation Products in Plasma of Drug-Naive Patients at the Onset of Psychosis, International Congress on Schizophrenia Research, Warm Springs, Virginia, 08-12 April 1995.

Scheffer R, Mukherjee S, Mahadik SP, and Correnti EE: Effects of Neuroleptic Treatment on RBC Activities on Antioxidant Enzymes, International Congress on Schizophrenia Research, Warm Springs, Virginia, 08-12 April 1995.

Scheffer RE: Low Plasma Homovanillic Acid at the Onset of Psychosis, Thirteenth Annual Resident Research Day, EAMC, Fort Gordon, Georgia, 24 May 1995.

Correnti LM: Teaching Marital and Family Therapy Skills to General Psychiatry Residents, 1995 AADPRT Midwinter Meeting, Tucson, Arizona, 13 January 1995.

Correnti, LM: Children's Mental Health Issues in Cuban and Haitian Refugees, 1995 US Army Behavioral Science Short Course, Miami, Florida, 24 August 1995

Slayton J, McClure MJ: Teaching Residents How to Teach, Annual Meeting of American Association of Directors of Psychiatry Residency Training, Tucson, Arizona, 8-12 February 1995.

Scheffer RE, Correnti EE, Mahadik SP, McClure M, Mukherjee S: Memberane Lipid Peroxidation and Neurological Signs in First-Episode Psychosis. Annual Meeting of the Society of Biological Psychiatry, Miami, FL, May 1995.

Mukherjee S, Casanova MF, Crapanzano K, Scheffer RE, Correnti Ee, Bates PR, Mahadik SP, Mahadik J: Mitogenic Response to bFGF and Cerebral Volume in Psychotic Patients. Annual Meeting of the Society of Biological Psychiatry, Miami, FL May 1995.

Scheffer RE, Borison RL, Correnti EE, Diamond BI, Mahadik SP, Mukherjee S: Plasma HVA and Lipid Peroxidation Products in First-Episode Psychosis. Annual Meeting of the Society of Biological Pychiatry, Miami, FL, May 1995.

Mukherjee S, Sinha D, Bates PR, Scheffer RE, Correnti EE, Mahadik SP, Mahadik J: Abnormal Growth of Cultured Skin Fibroblasts from Psychotic Patients. Annual Meeting of the Society of Biological Psychiatry, Miami, FL May 1995.

Gowda S, Mukherjee S, Mahadik S, Correnti Ee, Scheffer R: Oxidative Injury at the Onset of Psychosis. Annual Meeting of the American Psychiatric Association, Miami, FL May 1995.

Scheffer RE, Correnti EE, Mukherjee S, Mahadik S: Neurodevelopment of Schizophrenia: The First-Episode Psychosis Study. Behavorial Science Postgraduate Short Course, Miami, FL August 1995.

DEPARTMENT OF RADIOLOGY

Spirnak JP, Nieves N, Hollsten DA, White WC, and Betz TA: Gadolinium-enhanced Magnetic Resonance Imaging Assessment of Hydroxyapatite Orbital Implants, 95th Annual Meeting American Roentgen Ray Society, Washington, DC, 30 April-05 May 1995.

DEPARTMENT OF SURGERY

General Surgery Service

St. Jean M: Pre-operative Localization of Parathyroid Adenomas with Technetium 99m Sestamibi Scintigraphy, 63rd Annual Scientific Meeting of the Southeastern Surgical Congress, New Orleans, Louisiana, 03-10 February 1995.

Miller SK: The Effects of Ectreotide on Wound Healing of Small Bowel Anastomosis, 63rd Annual Scientific Meeting of the Southeastern Surgical Congress, New Orleans, Louisiana, 03-10 February 1995.

Miller S: The Effects of Octreotide on Wound Healing of Small Bowel Anastomosis, Georgia Chapter of the American College of Surgeons, Sea Island, Georgia, 23-26 March 1995.

Workman C: The Natural History of Gallstones in the Peritoneal Cavity Following Cholecystectomy in the Rabbit Model, Georgia Chapter of the American College of Surgeons, Sea Island, Georgia, 23-26 March 1995.

Waddell BE: Adjuvant Therapy for Node-Negative Breast Cancer: Impact of the 1990 NIH Consensus Development Conference, Georgia Chapter of the American College of Surgeons, Sea Island, Georgia, 23-26 March 1995.

Waddell BE: Adjuvant Therapy for Node-Negative Breast Cancer: Impact of the 1990 NIH Consensus Development Conference, 48th Annual Cancer Symposium, Boston, Massachusetts, 23-26 March 1995.

Waddell BE: The Epidemiology of Thyroid Cancer in the United States: A Tumor Registry Review from 1989 to 1993, The 1995 Annual American Radium Society Meeting, Paris, France, 28 April-05 May 1995.

Miller SK: The Effects of Octreotide on Healing of Small Bowel Anastomosis, Thirteenth Annual Resident Research Day, EAMC, Fort Gordon, Georgia, 24 May 1995.

Taylor T: Mechanism of Ventilator-Induced and Bacterial Translocation Across the Respiratory Membrane in the Porcine Model, Thirteenth Annual Resident Research Day, EAMC, Fort Gordon, Georgia, 24 May 1995.

Neurosurgery Service

Lee M: Neuroendoscopy, Tenth Annual MCG Neurosurgery Resident's Reunion, Augusta, Georgia, 03-04 February 1995.

Lee M, Rezai AR, Freed D, Miller DC, Wisoff, JH: Determinants of Progression-Free Survival Following Surgical Resection of Low-Grade Hypothalamic Gliomas, 63rd Annual Meeting of the American Association of Neurological Surgeons, Orlando, Florida, 22-27 April 1995.

Lee M, Rezai AR, Freed D, Wisoff JH, Epstein FJ: Clinical Factors Associated with Perioperative Morbidity in Children with Hypothalamic Tumors, 63rd Annual Meeting of the American Association of Neurological Surgeons, Orlando, Florida, 22-27 April 1995.

Lee M. Zagzag D, Rezai AR, Wisoff JH, Epstein FJ: Histological Correlates of Radiographic Imaging Characteristics for Cystic Cerebellar Astrocytomas in Children, 63rd Annual Meeting of the American Association of Neurological Surgeons, Orlando, Florida, 22-27 April 1995.

Lee M, Zagzag D, Allen JC, Rezai AR, Epstein FJ: Primitive Neuroectodermal Tumors of the Brain Stem, 63rd Annual Meeting of the American Association of Neurological Surgeons, Orlando, Florida, 22-27 April 1995.

Rezai AR, Woo HH, Zagzag D, Epstein FJ: Disseminated Ependymomas of the Central Nervous System, 63rd Annual Meeting of the American Association of Neurological Surgeons, Orlando, Florida, 22-27 April 1995.

Orthopaedic Service

Sladicka SJ: A Radiographic Comparison of Adductor Tenotomy Versus Adductor Transfer for the Treatment of Hip Subluxation in Cerebral Palsy, 28th Annual Resident's Conference of the American Orthopaedic Association, Pittsburgh, Pennsylvania, 29 March-01 April 1995.

Legan J: Antibiotic Impregnated Spaces for Use in Infected Total Joints, Annual Society of Air Force Clinical Surgeons Symposium, Dayton, Ohio, 24-27 April 1995.

Cresci A: Medial Subtalar Dislocation, Society of Armed Forces Podiatric Meeting, Rockville, Maryland, 26-28 April 1995.

Sladika SJ: A Radiographic Comparison of Adductor Tenotomy versus Adductor Transfer for the Treatment of Hip Subluxation in Cerebral Palsy. SOMOS 36th Annual Meeting, Hilton Head, South Carolina, November 1994.

Sladika SJ: A Biomechanical Strength Comparison of External Fixators (Poster) 1st Annual 1995 Trauma Symposium. San Antonio, Texas, September 1995.

Taylor DC: Arthroscopic Evaluation of First-Time, Traumatic Anterior Dislocations of the Shoulder, 1995 Annual Meeting of the Arthroscopy Association of North America, San Francisco, California, 04-07 May 1995.

Raab MR: Continuous Passive Motion after Rotator Cuff Repair, 1st Annual DDEAMC Hand Day, Fort Gordon, Georgia, 24 May 1995.

Travis MT: Keinbock's Disease, 1st Annual DDEAMC Hand Day, Fort Gordon, Georgia, 24 May 1995.

Benfanti PB: The Effect of Intraoperative Hip Position on Maintenance of Lumbar Lordosis, Thirteenth Annual Resident Research Day, EAMC, Fort Gordon, Georgia, 24 May 1995.

Benfanti PB: The Effect of Intraoperative Hip Position on Maintenance of Lumbar Lordosis, The 1995 Scoliosis Research Society Meeting, Asheville, NC, September 1995.

Benfanti PB: Syrinx-Like Artifacts on MRI - The Gibb Phenomena. The 1995 Scoliosis Research Society Meeting, Asheville, NC, September 1995

Kragh JF: Parachuting Injuries Among Army Rangers: A Prospective Survey of an Elite Airborne Battalion, Thirteenth Annual Resident Research Day, EAMC, Fort Gordon, Georgia, 24 May 1995.

Kragh JF: Clinical Use of Bone Allografts in Periodontics and Orthopaedics, Part II, Use of the KT-2000 and Microextensometers. The 19th Annual Meeting American Association of Tissue Banks, Atlanta, Georgia, 9-13 September 1995.

Raab MG: Moderator, Society of Military Orthopedic Surgeons Thirty-Sixth Annual Meeting, "Hand Surgery" and "Foot and Ankle", Hilton Head Island, SC, November 13-18, 1994.

Raab MG: Postoperative Toxic Shock Syndrome, American Academy of Orthopedic Surgeons 61st Annual Meting, New Orleans, LA, February, 1994.

Petersen SA, Jahnke AH, Neumann CH: MRI of the Glenohumeral Joint: Pitfalls in the Diagnosis of Labral Pathology. Presented 6th International Congress on Shoulder Surgery, Helsinki, Finland, July 1995.

Jahnke AH, Petersen SA, Neumann CH: Diagnostic Imaging of Glenohumeral Instability: MRI vs CT Arthrography. Presented 6th International Congress on Shoulder Surgery, Stockholm, Sweden, July 1995

Petersen SA, Jahnke AH, Neumann CH: MRI Findings in Anterior Glenohumeral Subluxation and Dislocation. Presented at 6th International Congress on Shoulder Surgery, Helsinki, Finland, July 1995.

Cresci AB: Subtalar Joint Dislocations. Society of Armed Forces Podiatrist, Rockville, Maryland 25-27 April 1995.

Alitz C: Surgical Treatment of Knee dislocations: A Series of Nine Patients., SOMOS, Hilton Head Island, SC, Dec 1994

OB/GYN

Apodaca CC: The Obstetric Care of a Patient in a Prolonged Vegetative State. The ACOG/AFD Conference, San Diego, CA 4-7 October 1995.

HEALTH PHYSICS

Marx DL and Balter S: The Distribution of Stray Radiation in a Cardiac Catheterization Laboratory, Joint Annual Meeting of American Association of Physicists in Medicine Health Physics Society, Boston, Massachusetts, July 1995.

DETAIL

SUMMARY

SHEETS

DETAIL SUMMARY SHEET

Date:	1 Sep 95	Protocol	87-40	**Status**	Terminated
Title:	Pathology Applications of X-ray Spectrometric Microanalysis				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Jack A. Horner, BS			**Facility:** Eisenhower Army Medical Center		
Department/Service: Clinical Investigation/Pathology			**Associate Investigators:** Phyllis Brewer, DAC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Terminated		

Study Objective: To utilize specimens obtained during routine surgical and autopsy pathology examinations to gain expertise in applications of x-ray spectrometric microanalysis.

Technical Approach: Tissue specimens without known abnormalities of elemental composition are selected from the daily laboratory workload. These are examined for establishment of baseline spectrometric spectra following the use of various fixatives. These spectra can then be compared against specimens with known or suspected elemental abnormalities.

Progress: Sixteen additional samples were added to the data base. The use of these techniques for blood/lead determinations will be investigated in the near future. Suitable reference standards are being planned and prepared.

DETAIL SUMMARY SHEET

Date: 1 Sep 95 **Protocol** 89-38 **Status** Ongoing	
Title: Non-ionic Surfactants in the Treatment of Third Degree Burns in Rats	
Start Date: Jul 89	**Est. Compl. Date:**
Principal Investigator(s): James C. McPherson III, PhD	**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation	
Key Words: Surfactant Burn treatment	**Associate Investigators:** James C. McPherson, Jr., MD Kent M. Plowman, MD, COL, MC Paul W. Paustian, MD Royce R. Runner, MT (ASCP) R. R. Haase, MAJ, MC
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To study potential protective effects on non-ionic surfactants in the treatment of third degree burns.

Technical Approach: Effect of single and multiple doses of non-ionic surfactants given IV thirty minutes following a full thickness burn will be studied to evaluate burn wound healing.

Progress: Continue to evaluate pluronic polyols in third degree burns using various doses and administration techniques. This protocol has resulted in the presentation of papers at the Army Science Conference and the meeting for Academic Emergency Medicine. Research continues.

Problems Encountered: Histologic evaluations are difficult to obtain due to lack of appropriate trained personnel.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 91-19	**Status** Ongoing	
Title: Development of a Heat Stroke Model in the Rat and Treatment with Pluronic Polyols			
Start Date: Jan 91		**Est. Compl. Date:** Jan 93	
Principal Investigator(s): James C. McPherson III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** A. Henry Chuang, PhD Paul W. Paustian, MD James C. McPherson Jr, MD	
Key Words: Heat stroke, Pluronic polyols			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To evaluate a new model for the production of heatstroke in the rat that will be more consistent in pathophysical parameters, will require less time to develop and will control the biological variation in the model. It will also study the effect of treatment of two pluronic polyols versus saline as the resuscitative fluid in heatstroke victims (in this case rats).

Technical Approach: Fur will be removed from the rat and the rat allowed to swim in a heated water bath. Pluronic polyol solutions or saline will be administered as resuscitative fluids. The pluronic polyols have been shown by investigators in this laboratory to have membrane protective properties and have been proposed for use as resuscitative agents.

Progress: Comparison to female model was begun in summer 1995. Initial literature indicates a sex difference between male and female to heat stroke.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 91-37	**Status** Ongoing	
Title: The Effect of Pluronic Polyols on Experimental Edema Produced by Various Means: Arachidonic Acid, Carrageenin, Histamine and Thermal Injury. A Study in Rats and Mice.			
Start Date: Jan 91		**Est. Compl. Date**	
Principal Investigator(s): James C. McPherson III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Royce R. Runner, ASCP A. Henry Chaung, PhD Paul W. Paustian, MD James C. McPherson Jr, MD	
Key Words: Edema Pluronic polyols			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: Previous investigations in this laboratory supported decreased skin edema in third degree burns. In this study we will investigate both pre- and post-injury IV administration of pluronic polyols on ear, skin and paw edema.

Technical Approach: Ear edema will be produced by topical application of the edema causing agents. Paw edema will be produced by injection of the edema causing agents into the foot pad or by thermal injury. Intradermal and topical applications of these agents will be used on the skin. Both pre- and post-injury IV administration of pluronic polyols will be utilized. Edema formation will be measured over time using a fluid displacement method for the paw and a micrometer caliper for the ear.

Progress: Resident presented data at National Meeting indicating both pre and post treatments of thermal injuries with pluronic polyols significantly limiting edema formation. Data is basis for grant proposal already submitted to USN.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 92-15	**Status** Ongoing	
Title: Cell Membranes and the Gastric Mucosa from Sodium Fluoride in the Rat			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): A. Henry Chuang, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James C. McPherson III, PhD Royce R. Runner James C. McPherson, Jr., MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To investigate the effects of fluoride ion on red blood cells and the gastric mucosa in the rat. Also to evaluate the effects of pluronic polyols when the red blood cells and the rats are treated with sodium fluoride.

Technical Approach: Fresh heparinized rat red blood cells will be incubated in buffered isotonic sodium chloride and sodium fluoride solutions with or without the presence of pluronic polyol, F-68. At various time intervals the percent of hemolysis of red blood cells will be determined. Sodium fluoride solutions will be administered orally to the rats. The stomach and small intestine from the rats treated orally or IV with pluronic polyol, F-127 will be compared with those without F-127.

Progress: The results of the histological study clearly show an effective protection of Omeprezole on the stomach mucosa under toxic level of sodium fluoride. It increases the pH of gastric fluid from pH 3 (the control group) to pH9-0.

Problems Encountered: The quantitative measurement of gastric mucus with Alcain blue requires further refinement.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-33	**Status** Ongoing	
Title: Endogenous Lipemia and Chemo Prevention in Breast Cancer			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): A. Henry Chuang, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James McPherson, III James McPherson, Jr. B.B. Single, MCG	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To be a conducive physiological/biochemical condition to mammary tumorigenesis.

Technical Approach: A rodent model will be used to answer if hyperlipemia caused either by intake of HFD or induced endogenously by surfactants, TWR1339 or pluronic F-127, is a possible causal factor of mammary tumors.

Problems Encountered: No study has yet been conducted pending potential extramural funding.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-34	**Status** Closed
Title:	Breast Cancer Gene Therapy: Transferring Tumor Suppressor Genes into Cancer Cell in-vitro and in-vivo with Viral Carrier Vector (Rats and Mice)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Charles Cheng, MCG		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James McPherson, III, PhD A. Henry Chuang Antonio Milici, MCG	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To establish the parameters needed for tumor suppressor genes to establish the parameters needed for tumor suppressor genes P53 and RB to inhibit the action of oncogenes in vitro and in vivo.

Technical Approach: Phase I: establish a working model with transformed mammary cells in culture to assess the tumor suppressing action of P53 and RB. Phase II: find an efficient retro-viral carrier system to deliver these genes to the host tumor tissues; and Phase III: deliver tumor suppressor genes P53 and RB by retroviral vectors into tumor bearing transgenic mice or syngenic rat.

Subjects enrolled to date: Nineteen.

Problems Encountered:

Progress: Nineteen subjects have been enrolled in 5 stages of HIV infection. All tested in duplicate with p53 ELISA. No apparent pattern evolved in stage vs. p53 level.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-50	**Status** Ongoing
Title:	The Effect of Levonorgestrel (Norplant) on the Immune Regulation of Bone Morphogensis in Calverial Cultures from the Laboratory Mouse (Mus Musculus)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): David W. Craft, MAJ, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Henry Chuang, PhD LTC Him W. Strider, DE LTC Benjamin S. Hanson, DE MAJ Steven W. Tobias, DVM Norma H. Best, BS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To study the incidence of post-operative localized osteitis due to molar extraction in female soldiers using NORPLANT for birth control.

Technical Approach: To study the immune regulatory effect of levonorgestrel on cultured cells involved in bone morphogenesis. The study will move the lab close to being able to grow the cells in continuous culture and reduce the future need for animals for certain bone studies.

Progress: Technique development and pilot studies completed. Varying levels of Levonorgestrel appear to down regulate IL-6 production vs control (non-treated cells) and versus progesterone treated (positive control) cells. Further studies characterize response in IL-IB treated cells.

Problems Encountered: Appropriate tissue culture media trials required an increase in animals - approved 13 Apr 95. This research is funded by Defense Women's Health grant dollars. Study should, therefore, conclude by end of FY95.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-51	**Status** Ongoing	
Title: Women's Health Care Issues: Heatstroke in Rattus Norvegicus			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): James C. McPherson, III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** A. Henry Chuang, PhD Royce Runner, Medical Technologist James C. McPherson, Jr., M.D. MAJ Steven Tobias, VC PFC Demetrius Collins, Vet Technician	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To evaluate a new model for the production of heatstroke in the rat that will be more consistent in pathophysical parameters and will control for the biological variation in the animal model. Will also study the effect of treatment of two poloxamers versus saline as the resuscitative fluid in heatstroke victims (rats).

Technical Approach: A therapeutic intervention is proposed using poloxamers, compounds that have been shown to protect the red blood cell membrane and decrease interstitial edema in burns. In addition to normal female rats, additional female rats will have their hormonal states altered to access the effects of hormones on heatstroke. This model can be utilized to study various pharmacological and biochemical parameters and functions concurrently.

Progress: Preliminary experiments performed for submission to USAMRDC funding.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-52	**Status** Ongoing
Title:	The Application of Non-ionic Surfactants to Wound Healing and Inflammatory States in the Diabetic Animal (Rates: Rattus Norvegicus and Mice: (Mus Musculus)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): James C. McPherson, III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Royce Runner, Medical Technologist James C. McPherson, Jr., M.D. MAJ Steven Tobias, VC PFC Demetrius Collins, Vet Technician	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To determine if administration of poloxamders 188 or 407 will improve the rate of early wound healing in diabetic animals, both animals with chemically induced diabetes and animals which have genetic diabetes.

Technical Approach: Will compare wound healing in all types of injuries proposed in untreated alloxan diabetic rats (controls) and streptozotocin diabetic rats (controls).

Progress: Resident assigned to wound healing in diabetic animals.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-53	**Status** Ongoing
Title:	Training for Department of Clinical Investigation and Veterinary Services Personnel in Medical, Surgical, and Emergency Care and Treatment, and Laboratory, Pathology, and Radiologic Procedures for Various Laboratory Animal Species		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Steven W. Tobias, MAJ, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** COL James Elmore, DVM	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To provide training in routine and emergency medical, surgical, laboratory, pathology and radiology procedures for personnel of the Department of Clinical Investigation and Veterinary Services, using government owned animals.

Technical Approach: Use colony animals only for procedures which do not require euthanasia. A variety of animal use protocols require that the personnel providing this support have some measure of proficiency and competency in the performance of tasks associated with conducting these studies. It is necessary for personnel to learn new tasks, new methods, new procedures, or combinations thereof. It is necessary for personnel to practice skills which they already possess to establish a means for utilizing available animal resources to obtain this required training.

Subjects enrolled to date: None

Problems Encountered: None

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-54	**Status** Ongoing	
Title: Measurement of Calcium/Bone Loss Under Stressful Conditions in Female Soldiers During Deployment Utilizing Rattus Norvegicus as a Model			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): A. Henry Chuang, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James C. McPherson, III, PhD Royce Runner, Medical Technologist James C. McPherson, Jr., M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To investigate the bone strength and bone calcium in female rats subjected to various stresses (physical exercise, heat, electric shock and noise) to mimic certain stressful conditions which the female soldier may encounter during deployment.

Technical Approach: In part I of this study on the measurement of calcium and bone loss under stressful conditions in females, will investigate the changes of calcium content in bone, bone strength and bone density in young adult male and female rats under various stressors at different intensities and through different durations.

Progress: No studies have been conducted pending potential extramural funding.

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-59	**Status** Ongoing
Title:	A New In Vitro Model Using Laboratory Mouse (Mus Musculus) Osseous Cells and An In Vivo Animal Model (Rattus Norvegicus) for Evaluating Biocompatability and Cytotoxicity of Dental Impression Materials		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Dennis A. Runyan, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** LTC Benjamin S. Hanson, DE LTC Stephen M. Cameron, DE COL David M. Lewis, DE MAJ David W. Craft, MS MAJ Steven W. Tobias, MS, DVM	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To investigate the biocompatibility and cytotoxicity of several dental polymeric impression materials, including three different polyvinylsiloxanes, a polyether, and a polysulfide rubber.

Technical Approach: This study will focus on the effects on osteoblasts and bone. All animals in each group will be randomly selected. Which holes are unfilled or filled will be arrived at by random selection. This manner will allow confound location as a potential extraneous factor. Rats will be administered tetracycline immediately post-operatively to mark the bone levels at the time of surgery. Rats will be allowed to heal for 120 days on normal diets. The mouse fetal osteoclasts will be harvested for use in cell culture. Post-operative pain will be monitored by behavioral criteria with analgesics administered required.

Progress: Animal requirements are completed. Data collection on-going.

Problems Encountered:

DETAIL SUMMARY SHEET

Date: 13 Apr 95	**Protocol** 91-9	**Status** Closed	
Title: Wear and Cutting Efficiency of Sonic Files			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Leander Lanier, Sr, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** James C. Kulid, COL, DE Robert J. Loushine, COL, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To evaluate the wear of Shaper-sonic files after use in vitro in a simulated root canal in bovine bone and relate this wear to its cutting efficiency.

Technical Approach: Simulated root canals will be prepared from a single bovine femur. Forty-five specimens will be prepared 3x2x2cm using a band saw. The specimens will be maintained in a solution of 0.2% sodium azide to prevent bacterial growth.

Progress: Resident graduated, completed groups A & C but not B. Study completed.

DETAIL SUMMARY SHEET

Date:	13 Apr 95 **Protocol** 94-11		**Status** Closed
Title:	Comparison of Nickel: Titanium Finger Spreaders to Conventional Spreaders for the Ability to Approach the Apex of Curved Canals.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Keith A. Berry, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Patricia D. Primack, COL, DE Robert J. Loushine, COL, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: This study proposes to demonstrate the advantages that flexible endodontic spreaders can offer when compared to still conventional spreaders to approach the working length of prepared curved canals.

Technical Approach: Fifty mandibular molars will be selected by virtue of having mesial aroots with a curvature of at least thirty degrees. The teeth will be stored in 10% neutral buffered formalin.

Progress: Twenty experimental teeth cleaned and shaped. Radiographic measurement of spreader lengths in canals made will complete the project.

DETAIL SUMMARY SHEET

Date:	13 Apr 95 **Protocol** 94-87		**Status** Closed
Title:	Effects of Root Canal Sealing Materials in Laboratory Mouse (Mus Musculus) Osseous Cells		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): William R. Patton, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Patricia D. Primack, COL, DE Robert J. Loushine, COL, DE Benjamin S. Hanson, OCL, DE David W. Craft, MAJ, PhD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: The objective of this study is to investigate the biocomopatibility and cytotoxicity of five different root canal filling materials including three different sealers and two types of gutta percha. Previous studies have focused on the effects of these materials on fibroblasts and soft tissue. We propose to study the immune regulatory effect of these dental materials on cultured cells involved in bone morphogenesis

Technical Approach: Specific activity of bone producing cells, or osteoblasts, will be analyzed by staining for alkaline phosphatase activity. Growth media from the cell cultures will be sampled, stored at -70^{0}C and later assayed for IL-6 and osteocalcin presence.

Progress: All data collected. Study closed

DETAIL SUMMARY SHEET

Date: 13 Apr 95	**Protocol** 94-88	**Status** Completed	
Title: Effects of Root Canal Sealing Materials in Laboratory Mouse (Mus Musculus) Osseous Cells			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Stephen M. Cameron, COL, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** John R. Agar, COL, DDS James C. Hughbanks, COL, DMD Max L. Gaston, OCL, DDS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continued	

Study Objective: This study will investigate and compare the surfaces of abutments following the removal of three different coments using three different instruments in vitro.

Technical Approach: This part of the study will replicate the in-vitro study in-vivo.

Progress: Project was not funded and is now closed.

DETAIL SUMMARY SHEET

Date:	13 Apr 95 **Protocol** 95-7		**Status** Ongoing
Title:	An Investigation of the Inhibiting Effects of Gallium Nitrate on Bone Resorption Using Human Root Dentin and Osteoclast-like Multinucleated Cells from the Laboratory Mouse (Mus musculus) In-vitro.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): John Buyer, Jr, MAJ, DDS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** David W. Craft, MAJ, PhD, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continued	

Study Objective: This study will determine whether gallium will prevent the osteoclast-like cell from resorbing dentin. If this is successful, an animal model may be designed by a future investigator and potential applications of gallium in the treatment of local bone problems may be possible.

Technical Approach: This experiment will follow a resorptive assay developed by Tamura et al. Cocultures of mouse primary osteoblasts and marrow cells are used to form osteoclast-like multinucleated cells (MNC).

Progress: An approval to order 20 ICR outbred non-pregnant mice for long bone marrow harvesting was approved by the IACUC. Initial osteoclast co-culture results have been very successful and we feel it is necessary to compare our results using time pregnant mice to non-pregnant mice. We suspect our protocol is vastly superior to any other published osteoclast co-culture systems.

DETAIL SUMMARY SHEET

Date: 13 Apr 95	**Protocol** 95-3	**Status** Ongoing	
Title: An Investigation of the Inhibiting Effects of Gallium Nitrate on Bone Resorption Using Human Root Dentin and Osteoclast-like Multinucleated Cells from the Laboratory Mouse (Mus musculus) In-vitro.			
Start Date: Dec 94		**Est. Compl. Date:**	
Principal Investigator(s): Richard J. Windhorn, MAJ, DMD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Stephen M. Cameron, COL, DDS Max L. Gaston, COL, DDS Merle H. Parker, COL, DDS Michael R. Craddoxk, MAJ, DDS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continued	

Study Objective: The purpose of phase I of this study is to determine whether or not there is a difference in bond strengths of ethced Empress ceramic after being refired in a porcelain oven for modification. Phase II of the study will determine whether or not there is a difference in bond strengths of different etchant materials and etchant times on Empress ceramic.

Technical Approach: Shear bond strength will be calculated for Phase I and II by recording the amount of force (in Newtons) requried to cause fracture per surface area (in cm^2) of the bonded specimens. Results will be expressed in MegaPascals (MPa).

Progress:

DETAIL SUMMARY SHEET

Date: 13 Apr 95	**Protocol** 95-24	**Status** Closed	
Title: A Direct Digital Radiography System Compared with Conventional Radiography in Canal Length Determination.			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): James Mistak, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Patrice D. Primack, COL, DE Robert J. Loushine, COL, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To evaluate and compare the RadioVisualGraphy (RVG) system to conventional to radiography in root canal length determination and evaluation of artificial bone lesions.

Technical Approach: Artificial bone lesions will be created in human cadaver specimens and radiographed conventionally and with RVG.

Progress: Data collection completed.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 91-62	**Status** Closed	
Title: Parotid Gland Biopsy and Transbronchial Lung Biopsy in the Diagnosis of Sarcoidosis: A Comparison Study			
Start Date: Jul 91		**Est. Compl. Date:**	
Principal Investigator(s): R. Terry Ellis, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dentistry, Pulmonary		**Associate Investigators:** Michael W. Tabor, COL, DC David M. Lewis, COL, DC Warren L. Whitlock, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To relate the involvement of the lungs and parotid gland in sarcoidosis.

Technical Approach: Patients with strong suspicion of sarcoidosis undergo open biopsy of parotid and transbronchial lung biopsy under intravenous sedation. OMS Staff or residents perform intravenous sedation and parotid gland biopsy, then transbronchial lung biopsy is performed by Pulmonary Staff physicians. Tissues are then evaluated by COL David Lewis, Staff Oral Pathologist.

Manpower: Existing clinic staff is utilized.

Number of subjects enrolled to date: 21

No adverse reactions.

Progress: Currently continuing to enroll subjects.

DETAIL SUMMARY SHEET

Date: 12 Jan 95	**Protocol** 95-5	**Status** Closed	
Title: Disinfection of Denture Internal Surface			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): James J. Lin, DMD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To investigate whether the interior of acrylic resin removable dentures can be effectively disinfected during a routine chair-side disinfection procedure using Alcide LD disinfectant.

Technical Approach: Forty rectangular samples will be formed from baseplate wax. They will be flasked and processed using Ch Lucitone denture base resin following manufacturer's instructions.

Number of Subjects Enrolled to date:

Progress: Data collection completed.

Problems Encountered:

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 92-56	**Status** Closed	
Title: A Clinical Evaluation of Autogenous Iliac Bone Grafts in Periodontal Osseous Defects			
Start Date: Jun 92		**Est. Compl. Date:** Jun 94	
Principal Investigator(s): Benjamin S. Hanson, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** William Brennan, COL, DC	
Key Words: Periodontitis, Iliac graft			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To investigate the feasibility of the use of autogenous frozen marrow as a treatment modality in periodontal osseous defects.

Technical Approach: Twenty patients with hopeless teeth will be asked to participate in this study. Bone will be harvested from the ilium and stored in MEM at -6 C. Seven days after the cores have been taken they will be placed in periodontal defects.

Number of subjects enrolled to date: 11

Progress: Continuing to enroll patients.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol#** 92-58	**Status** Closed	
Title: A Comparison of the Clinical Success of the 5mm Nobelpharma Implant Fixture to the Standard 3.75mm Fixture			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Eric Adrian, LTC, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To study the clinical success of the 5mm fixture at 1, 2 and 3 year intervals.

Technical Approach: Clinical and radiological parameters will be used to compare the new fixture to the 3.75mm fixture.

Number of subjects enrolled to date: 15

Progress: Data collection completed.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 92-77	**Status** Closed	
Title: The Effect of Transforming Growth Factor Beta (TGF-B) in Conjunction with Polyols on Wound Healing Rats			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): George E. Tolson IV, LTC, DC		**Facility:** Animal Support Facility, Clinical Investigation	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To examine the effects of parenterally administered Transforming Growth Factor Beta in combination with topically applied pluronic polyols F-68 and F-127 on the tensile strength and healing of incisional wounds in the rat.

Technical Approach: Various concentration of F-68 and F-127 are applied to a standard wound in a rat. The tensile strength of the incision is then determined with the Instrom unit at the time of sacrifice.

Progress: Completed wound tensile strength studies; currently processing and staining tissue samples for PCNA, collagen, and factor 8.

Problems Encountered: (1) Delays in obtaining stain kits; and (2) it has been found that formalin fixed tissue over 2-3 days do not react well with the intranucleur stains. Antigen retrieval has provided limited success. Difficulties interacting with the histology section of the hospital concerning charging for histology services.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 93-12	**Status** Ongoing
Title:	The Effects of Transforming Growth Factor Beta and Platelet Derived Growth Factor on Human Gingival Fibroblasts and Human Periodontal Fibroblasts Grown in Serum and Serum Free Media		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Thomas J. Butts, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** William A. Brennan, COL, DC Benjamin S. Hanson, LTC, DC Michael A. Billman, LTC, DC Val L. Kudryk, LTC, DC Donald E. Sutherland, MAJ, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: Determine if the use of TGF-B & PDGF might enhance second healing.

Technical Approach: Fibroblast are grown in vitro and then cultured with TGFB or PDGF.

Progress: Cells are then surveyed for viability and growth. Presently gathering data.

DETAIL SUMMARY SHEET

Date: 1 Sep 95 **Protocol** 94-4 **Status** Completed			
Title: The Mechanism of Nicotine Suppression of Fibroblast Integrin Expression in Vitro			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Harold B. Snyder, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental	**Key Words:**	**Associate Investigators:** COL Michael Billman, DE LTC Benjamin Hanson, DE LTC Val Kudryk, DE MAJ David Craft, MS	
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To determine the mechanism of B1 integrin subunit suppression by nicotine.

Technical Approach: Human gingival fibroblasts will be cultured in different concentrations of nicotine. These concentrations will simulate levels or concentrations of nicotine which one would expect to find in the tissues of smokers. Newly synthesized B1 integrin subunits will be isolated, identified and quantitated in an effort to determine at what point during biosynthesis nicotine has a deleterious effect on B1 integrin expression.

Number of subjects enrolled for the reporting period:

Progress: Data collection completed. Thesis scheduled to defend in February 1996 at MCG.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-6	**Status** Closed
Title:	Evaluation of Pluronic Polyols on Regeneration in Rat Calvaria		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Edward Fowler, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael Billman, DE LTC Benjamin Hanson, DE LTC Val Kudryk, DE James McPherson, III, PhD Henry Chuang, PhD MAJ Steven Tobias, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To determine the effects of pluronic poyols on bone regeneration.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Animal procedure completed; specimens harvested. Scheduled to present project at Medical College of Georgia in Nov 94.

Problems Encountered: New methods of data collection added, problems encountered included coordination with experts in soft x-ray and digitization at VA and MCG respectively has taken about 2 1/2 months.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-8	**Status** Closed
Title:	The Effect of Dexamethasone on Human Gingival Fibroblast Proliferation, Collagen Production, and Integrin Expression and Distribution		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Val Kudryk, LTC, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael Billman, DE LTC Benjamin Hanson, DE MAJ David Craft, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To determine effects of various concentrations of dexamethasone on HGF proliferation.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Data collection completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-9	**Status** Closed
Title:	A Comparison of Endodontic Files After Cleaning with Dual Enzymatic Ultrasonic Cleaner and Conventional Detergent Ultrasonic Cleaner and the Evaluation for the Presence of Viable Bioburden After Autoclave and Chemical Vapor Sterilization: A Scanning Electron Microscope Study		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Mary Johnson, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** MAJ David Craft, MS Jack Horner, DAC Patricia Primack, COL, DE Robert Loushine, LTC, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To evaluate and compare the two ultrasonic cleaning methods for endodontic files: use of conventional detergent cleaner and the use of a dual enzymatic ultrasonic cleaner and to determine if any viable bioburden remains on the instruments after steam and chemical vapor sterilization.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Data collection completed.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-10	**Status** Closed	
Title: Sealing Ability of Bases and Cements Following Exposure to 30% Hydrogen Peroxide and Sodium Perborate			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Jeffery Luzader, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** LTC Patricia Primack, DE LTC Robert Loushine, DE Jack Horner, DAC Patricia Primack, COL, DE Robert Loushine, LTC, DE	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To identify a base or cement that will insulate standard root canal fillings from the degrading effects of 30% hydrogen peroxide and SP.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Data collection completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-12	**Status** Closed
Title:	Histological Response to Alloplast Implants in Extraction Sites in Pigs		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Glenn A. Greene, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** LTC James Strider, DE LTC Benjamin Hanson, DE COL David Lewis, DE MAJ David Craft, MS Jack Horner, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To determine if this alloplastic ingredient acts as an osseoconductive material or as a non-irritating filler.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Data collection completed.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-49	**Status** Ongoing	
Title: Women's Health Care Issues: The Incidence of Localized Osteitis in Female Soldiers Using Norplant Contraceptives			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Jim Strider, LTC, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Ricney Newhouse, DE MAJ Jim Duke, DE LTC Benjamin Hanson, DE LTC Dennis Runyan, DE James McPherson, III, PhD, DAC	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To compare and evaluate post-operative localized osteitis following molar extractions among patients who are currently being administered Levonorgstrel (NOR-PLANT) with the female population who are taking no systemic birth control.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Projected was funded, the data base of patients has been generated.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-57	**Status** Closed
Title:	Evaluating the Existence of Bennett Movement		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Michael Craddock, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael Craddock, DE COL Max Gaston, DE COL Stephen Hanson, DE LTC Merle Parker, DE	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To geometrically explain how Pantographic tracing artifacts mimicking Bennett's movement can be produced on pantographic tracing by rotational movement. Present a technique that can differentiate between pantographic tracing artifact and true Bennett's movement, thus providing the foundation for patient evaluation to confirm whether Bennett's movement actually exists or not.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Data collection completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95 **Protocol** 94-58		**Status** Closed
Title:	Effects of Thread Removal of Endosteal Implants Upon Shear Loading		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert Rosenheimer, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental/Clinical Investigation		**Associate Investigators:** COL Max Gaston, DE COL Stephen Hanson, DE LTC Merle Parker, DE	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To investigate the effect thread removal has upon the strength of a dental implant under shearing forces.

Technical Approach: Ten 15 millimeter Branemark titanium implants will be used in a pilot study to determine the statistically significant sample size (of implants) required for the study. Two groups of five implants will be established. Those in the first group of five will not be modified and serve as the control. The second group of five implants will have 5mm (measured from collar of the implant to its apical portion) of its threads removed, using a machining lathe with calibrated controls. Thread removal will be defined as complete when all remnants of the threads are deemed visually removed. Variations in the amount of thread removal will be recorded using a digital caliper. Values such as modules of elasticity, toughness, proportional limit, and ultimate shear strength will be compared for each of the two groups. All results will be statistically analyzed using a one way ANOVA.

Number of subjects enrolled for the reporting period:

Progress: Data collection completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-65	**Status** Ongoing
Title:	Women's Health Care Issues: The Effects of Estrogen Levels on Osseointegration of Dental Implants		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Benjamin Hanson, LTC, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** COL Michael A. Billman, DE LTC Larry Kudryk, DE COL Richney F. Newhouse, DE LTC Jim W. Strider, Jr., DE LTC Dennis A. Runyan, DE LTC Stephen M. Cameron, DE	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To compare and evaluate the success of dental implants in a female soldier population. The aim of the study is to determine if an associations exists between sex hormone levels and the osseointegration of dental implants.

Technical Approach: The patient population will be divided into three groups. The first group will consist of patients who are presently using systemic birth control. The second patient population will consist of individuals not employing systemic birth control. The third group will consist of male soldiers who will be enrolled in the study as a negative control.

Number of subjects enrolled for the reporting period:

Progress: Group 1 in the study consists of females taking oral contraceptives with endosseous dental implants placed mid-menstrual cycle. The availability of eligible patients requiring endosseous dental implants taking oral contraceptives has totalled 5 in number since the inception of the study. The screening process is ongoing and patient availability is poor.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-68	**Status** Ongoing	
Title: Wear and Cutting Efficiency of the Nickel Titanium Rotary Files			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Michael Ford, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** Frederick Rueggeberg, MCG COL Patrice Primack, DE Ronald Anderson, MCG Jack Horner, DAC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To determine the cutting efficiency of NT rotary files.

Technical Approach: All of the NT files will be viewed before initial use at 600X under the scanning electron microscope. The files and their corresponding flutes will be measured new, midrange and last use.

Number of subjects enrolled for the reporting period:

Progress: Model progressing well; well accepted by major advisor and research committee.

Problems Encountered: Change in test from bovine bone to a more homogenous ceramic.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-74	**Status** Ongoing	
Title: The Proteolytic Activity of Porphyromonas gingivalis and Prevotella intermedia Against Heme-binding Plasma Proteins			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): David R. Reeves, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** Geoffrey R. Tompkins, PhD, MCG COL Michael Billman, DE COL Benjamin S. Hanson, DE MAJ David W. Craft, MS	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To determine if P. gingivalis and P. intermedia possess an enzyme (proteolytic) that assists in the acquisition of heme even in the presence of heme-binding proteins that would seem to resist the acquisition of heme by the pathogens and if an enzyme (proteolytic) specific for heme-binding proteins exists, which protease inhibitors can be selectively added to the assay in order to decrease or eliminate the viability of the enzyme.

Technical Approach: The enzymatic activity of these bacteria will be tested (in vitro) against dialyzed whole human plasma. During incubation of the bacteria with plasma, samples will be separated and analyzed. The investigator has chosen to study hemopoxin and haptoglobin to test the possibility of P. gingivalis and P. intermedia break apart these hemopexin-heme and haptoglobin-hemoglobin complexes. Once these complexes are separated the bacteria may uptake and use the free heme. The investigator will analyze the enzymatic activity of these bacteria in order to assess this possibility and analysis will be made as to the potential chemical inhibitors of these enzymes.

Number of subjects enrolled for the reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-75	**Status** Closed
Title:	The Effects of Titanium Abutments of Cement Removal		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s):		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** LTC Stephen M. Cameron, DE COL James C. Hughbanks, DE COL Dennis A. Runyan, DE COL Max L. Gaston, DE	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Closed	

Objective: To investigate and compare the surfaces of abutments following the removal of three different cements (glass ionomer, resin, and zinc phosphate) using three different instruments (gold plated scaler, rigid plastic scaler, and stainless steel explorer).

Technical Approach: Five board certified prosthodonitsts will remove each cement using each instrument for a total of nine samples for each investigator. The investigators will determine the method for removing cements from titanium abutments that cause the least damage to the original, smooth, machined surface.

Number of subjects enrolled for the reporting period:

Progress: Data has been collected and submitted to the Journal of Prosthetic Dentistry.

DETAIL SUMMARY SHEET

Date:	08 Sep 94 **Protocol**	94-76	**Status** Ongoing
Title:	A Comparison of Two Impression Techniques for Accuracy of Occlusal Contacts		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Merle H. Parker, COL, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** LTC Stephen M. Cameron, DE COL James C. Hughbanks, DE COL Max L. Gaston, DE LTC David Reid, DE	
Key Words:			
Accumulative MEDCASE costs:		**Periodic Review Results:** Sep 95, Continue	

Objective: To investigate and compare the accuracy of interocclusal relationships of articulated casts from a closed mouth impression technique and a full arch conventional impression technique.

Technical Approach: Interocclusal records made with Blue-Mousse will be used for the evaluation. Each point of occlusal contact on the intraoral record will be visually identified and selected if it's thin enough to transmit light. An interocclusal record will be made from the articulated casts of each of the two impression techniques. For each of these points, the other two registrations will be evaluated to see if there is a corresponding point or not.

Number of subjects enrolled for the reporting period:

Progress: Data collection is essentially completed and the abstract will be submitted to the International Association of Dental Research.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-78	**Status** Ongoing	
Title: The Effects of Tetracyclines on Murine Bone Cell Cultures (Mus Musculus)			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Gary D. Swiec, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** MAJ David W. Craft, MS COL Michael A. Billman, DE COL Benjamin S. Hanson, DE LTC Val L. Kudryk, DE CPT Kim D. Vlach, MS, DVM SPC Demetrius Collins, Vet Technician	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To determine the effect of varying doses of tetracycline on mouse bone cells grown in a dish.

Technical Approach: The mice will provide an immature supply of bone cells which mimics the situation found around diseased human teeth during surgery, just prior to placement of the tetracycline/graft mixture. The investigator will harvest and grow bone cells from mice in 12-well plastic tissue cultures plates. Cell cultures grown both with and without tetracycline will be followed for 20 days. Cell cultures will be observed microscopically for growth. Specific activity of bone producing cells, or osteoblasts, will be analyzed by staining for alkaline phosphates activity. Growth media cell cultures will be sampled, stored at 70 degrees C and assayed for cytokine and osteocalcin presence. The results of this study will aid in the treatment of soldiers with periodontal disease.

Number of subjects enrolled for the reporting period:

Progress: Five experiments have been run since approval of this study. The range of TCN have narrowed from 250mg to less than 100mg. The yield of osteoblasts during Z digestions were lower than expected. This problem has been resolved.

DETAIL SUMMARY SHEET

Date:	21 Sep 95 **Protocol** 95-46		**Status** Ongoing
Title:	The Effects of Blood Sugar Levels on Osseous Regeneration in Sprague-Dawley Rats (Rattus Norvegicus) Grafted with Allograft.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Gregory A. Blythe, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** James C. McPherson, III, Ph.D Michael A. Billman, COL, DE Michael F. Cuenin, LTC, DE Val L. Kudryk, LTC, DE	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Ongoing	

Objective: To determine the effect of varying blood sugar levels on bone regeneration using allografts in rats.

Technical Approach: This study will look at bone regeneration in rats that have elevated blood glucose levels.

Number of subjects enrolled for the reporting period:

Progress: Data collection will begin in March 1996.

DETAIL SUMMARY SHEET

Date:	21 Sep 95 **Protocol** 95-43	**Status** Ongoing	
Title:	Effects of Nicotine on Expression of B Cell Leukemia/Lymphoma - 2 Proto-Oncogene (BCL2), P-53 Tumor Suppressor Gene and cFOS Proto-Oncogene Messenger RNA in Murine (Mus Musculus) Osteoblast Cells.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Stephen J. Rouse, MAJ, ED		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** Michael A. Billman, COL, DE Michael F. Cuenin, LTC, DE Val L. Kudryk, LTC, DE	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To determine the levels of three cell cycle regulators (BCL2,P-53 and cFOS) in bone forming cells during the phases of growth and in response to a chemical insult (nicotine).

Technical Approach: Mice are needed to supply an immature supply of bone cells that mimics the situation found around diseased human teeth. Bone cells will be harvested and grown from mice in plastic tissue culture plates.

Number of subjects enrolled for the reporting period:

Progress: Data collection will begin in March 1996.

DETAIL SUMMARY SHEET

Date:	21 Sep 95 **Protocol** 95-44		**Status** Ongoing
Title:	Evaluation of the Effects of Transforming Growth Factor Beta and Divinyl Benzene Beads on Osseous Regeneration in Rat Calvaria (Rattus Norvegicus)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Paul O. Francis, MAJ, DE		**Facility:** Tingay Dental Clinic	
Department/Service: Dental		**Associate Investigators:** Michael A. Billman, COL, DE Michael F. Cuenin, LTC, DE Val L. Kudryk, LTC, DE James C. McPherson, III, Ph.D	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To determine the effectof Transforming Growth Factor Beta (TGF-B) and Divinyl Benzene beads (DVBb) on osseous regeneration in rats.

Approach: Animals will be stabilized and isolated for 7 days prior to beginning the protocol. Following the surgical procedures, the animals will be observed for any signs of pain or distress.

Number of subjects enrolled for the reporting period:

Progress: Data collection will begin in March 1996.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-77	**Status** Ongoing	
Title: Emergency Medicine Trauma Lab (Sus Scrofa)			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert Suter, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Emergency Medicine		**Associate Investigators:** MAJ Jerry Fenwick, MC MAJ Sarah Mack, MC Joyce Norman, MD Ivy Shuman, MD Brendan O'Hara, MD F.P. Craig Miner, MD CPT Jeffrey Brasfield, MS, PA CPT Daniel Cruser, MC	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: The objective of this protocol will be basic proficiency training of physicians (interns and residents) working in the Emergency Department with necessary life-saving procedures and as a refresher proficiency training of staff health care providers. This lab will also reinforce skills learned in the ATLS course.

Technical Approach: Each session will consist of up to four interns/residents and will utilize one pig. Several standard procedures will be performed on the pig allowing maximal use of each pig when training physicians. The estimated number of procedures to be taught is up to 48 students per year during 12 sessions per year.

Number of subjects enrolled for the reporting period:

Progress: The lab is investigated monthly.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 95-25	**Status** Ongoing	
Title: Pregnancy Detection in the Emergency Department			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Paul T. Mayer, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Emergency Medicine		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE cost:		**Periodic Review Results:** Sep 95, Continue	

Objective: To determine the prevalence of unrecognized pregnancy in an Emergency Department setting and also to ascertain whether or not pregnancy testing of all females of reproductive age is justified using a prospective study of random women who report to the Emergency Department.

Technical Approach: A total of 2000 women in an age range from 10-55 will be tested. The current EAMC policy already tests urine HCG of all females presenting to the Emergency Department before any diagnostic or therapeutic action is taken. This data will be used to determine whether or not a patient history performed upon presentation by the health care provider can adequately detect unrecognized pregnancy.

Number of subjects enrolled for the reporting period:

Progress:

Detail Summary Sheet

Date: 1 Sep 95	**Protocol** 93-25	**Status** Closed	
Title: HELLP Syndrome: The Incidence - A Prospective Study			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth Trzepkowski, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice/OB-GYN		**Associate Investigators:** Wayne Blount, LTC, MC Keven Kelly, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To determine the incidence of HELLP and determining clinical characteristics associated with the development of the syndrome.

Technical Approach: Measure serum marers prospectively on volunteer pregnant patients.

Number of subjects enrolled to date: 199

Progress: No progress since last approval.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-40	**Status** Closed
Title:	Assessment of the Provision of Clinical Preventive Services and Immunizations		
Date:		**Est. Compl. Date:**	
Principal Investigator(s): Lynda A. Linker, COL, AN		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** COL Angela Dingbaum, AN Carol Gorman, RN, MCG LTC Wayne Blount, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Objectives: Review records to assess the current status of preventive services and immunizations received by patients at DDEAMC and to propose recommendations for methods, tolls, and/or programs to meet the objectives if the assessment indicates less than 50% of the patients have received the recommended services.

Technical Approach: (1) Assess the proportion of patients who have received the minimum clinical preventive services by reviewing a random sampling of outpatient medical records; (2) if results of assessments indicate less than 50% of the records document the minimum recommendations, develop proposals for methods, tool, and/or programs to assist health care providers with ensuring recommended clinical preventive services and immunizations are provided to their patients; and (3) if results of assessment indicate less than 50% of the records document the minimum recommendations, develop proposals for methods, tools, and/or programs to assist patients in assuming greater responsibility for their own health.

Number of subjects enrolled to date:

Progress: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 95-28	**Status** Ongoing
Title:	A Five Year Observational Study to Evaluate Clinical Response and Recurrence Rate in the Treatment of Basal Cell Carcinoma with Fluorouracil/Epinephrine Injectable Gel		
Date:		**Est. Compl. Date:**	
Principal Investigator(s): William L. Heimer, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Dermatology		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To describe the clinical response rate at three months post treatment, to describe the recurrence rate in patients with a clinical response at three months post treatment, and to confirm and evaluate the long-term safety and efficacy in patients with basal cell carcinoma.

Technical Approach: Each patient will have one lesion treated and evaluated. If more than one clinically diagnosed and/or biopsy proven eligible lesion is present, a randomization scheme for lesion selection will be used. Target enrollment for this institutionis 10-15 patients aged 18 years or older. Study duration will be at least four months, with extended follow up for up to five years.

Progress: Forty patients have been enrolled with the goal being fifty.

Problems encountered: None.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 91-14	**Status** Ongoing	
Title: Comparison of Intravenous H-2 Antagonists and Their Influence on Gastric Emptying on Insulin Dependent Diabetics			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Michael P. Goldfinger, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine		**Associate Investigators:** Eugene H. Ryan, CPT, MC, Staff Internist, Fort Rucker, Alabama Stephen G. Oswald, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To study the effect of a single standard IV dose of famotidine, cimetidine and ranitidine on GE in adult diabetics.

Technical Approach: Each patient will be studied in the fasting state on four different days spaced at least 72 hours apart. Prior to each gastric emptying study the subjects will receive an IV bolus injection of either one of cimetidine, ranitidine, famotidine, or placebo.

Number of subjects enrolled for the reporting period: 12

Problems Encountered: Difficulty getting adequate statistical support.

Progress: Statistical analysis presently being performed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95 **Protocol** 92-9		**Status** Closed
Title:	A Comparison of the Efficacy, Safety, and Tolerance of Ceftibuten (SCH 39720) 400 mg (I x 400 mg capsule) in the Fed and Fasted State and Augmentin Amoxicillin/Clavulanate 1.5 gm (I x 500 mg tablet TIC) in the Fed State in the Treatment of Acute Exacerbations of Chronic Bronchitis		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, MAJ, MC Jesse J. Doers, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To compare the efficacy, safety, and primarily, the GI tolerance of once-daily Cedax ceftibuten (SCH 39720) in both the fed and fasted state with that of Augmentin amoxicillin/clavulanate given TID in the fed state in the treatment of acute exacerbations of chronic bronchitis in adults.

Technical Approach: Treatment will follow outline in Schering-Plough protocol.

Subjects enrolled to date: 6

Progress: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 92-10	**Status** Closed
Title:	A Comparison of the Efficacy, Safety, and Tolerance of Ceftibuten (SCH 39720) 300 mg Given BID and Augmentin 500 mg Given TID in the Treatment of Community Acquired Pneumonia		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, MAJ, MC Jesse J. Doers, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To compare the efficacy, safety, and tolerance of high-dose ceftibuten (SCH 39720) 300 mg BID with that of augmentin 500 mg TID in the treatment of pneumonia in adults.

Technical Approach: Treatment will follow outline in Schering-Plough protocol.

Subjects enrolled to date: 5

Progress: None.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 92-30	**Status** Closed	
Title: Techniques of Use of Metered Dose Inhalers			
Start Date: Apr 92		**Est. Compl. Date:** June 93	
Principal Investigator(s): Richard B. Hilburn, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary Disease		**Associate Investigators:** Warren L. Whitlock, MAJ, MC Jesse T. Doers, MAJ, MC Ray Scarlett, CRT	
Key Words: MDI, Metered dose inhalers			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Closed	

Study Objective: To evaluate the techniques of use of MDI by the EAMC patient population. To determine which of three teaching modalities is the most effective in improving technique. To detect any implication of impact of improved technique upon emergency room visits and hospitalizations for the study population.

Subjects enrolled to date: 106

Problems Encountered: Forty percent patient drop-out due to enrollment of patients living outside EAMC catchment area.

Progress: A manuscript has been written. The statistical analysis is being rerun. The enrollment of patients is complete. Pending final statistical results.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 92-47	**Status** Ongoing
Title:	A Double-Blind, Placebo Controlled, Parallel Group, Multicenter Study of the Use of Weekly Azithromycin as Prophylaxis Against the Development of *Mycobacterium Avium Complex* Disease in HIV Infected People		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Daniel B. Craig, COL, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Infectious Disease		**Associate Investigators:** Craig E. Smith, MAJ, MC David R. Haburchak, COL, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To evaluate the safety and efficacy of azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromised HIV infected patients with a CD4 count<100/ul.

Technical Approach: Treatment will follow outline per Pfizer protocol.

Subjects enrolled to date: 9

Progress: Nine patients screened. One patient did not meet entry qualifications, one patient dropped from study before receiving drug, one patient died while on study not related to drugs. Six patients continue on study.

DETAIL SUMMARY SHEET

Date:	11 May 95 **Protocol:** 95-26	**Status**	Ongoing
Title:	A Double-Blind, Randomized, Phase 3, Multicenter Study of Suramin and Hydrocortisone versus Hydrocortisone and Placebo in the Treatment of Patients with Metastatic,Hormone-Refractory Prostate Carcinoma (Stage D2) (Protocol 1003-01)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Karen J. Bowen, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine		**Associate Investigators:** Stephen G. Oswald, COL, MC Kenneth I. Fink, LTC, MC Robert F. Krywicki, MAJ, MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To determine suramin's effect on pain, performance status, prostate specific antigen (PSA), measurable and osseous disease, quality of life, and survival in patients with hormone-refractory prostate carcinoma, and to evaluate the safety of suramin.

Technical Approach: Eligible patients will undergo a 2-week baseline period in which narcotic pain medications are stabilized. At the end of the baseline period, patients will be stratified prospectively on the basis of PSA level and presence of measurable disease and randomly assigned to the suramin or placebo treatment group.

Progress: Two patients enrolled this reporting period. Treatment has not been started on the first patient due to radiation therapy treatment.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95 **Protocol** 93-30 **Status** Closed		
Title:	A Multicenter Investigator Blinded Study of the Efficacy and Safety of Azithromycin vs Amoxicillin/Clavulanate in the Treatment of Acute Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease (Chronic Bronchitis)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, MD, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Jesse T. Doers, MD, MAJ, MC Wayne T. Honeycutt, MD, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To compare the safety and efficacy of orally administered azithromycin and amoxicillin/clavulanate in the treatment of acute exacerbations of COPD (Chronic Bronchitis) Caused by susceptible bacterial pathogens.

Technical Approach: Therapy will follow schema outlined in Pfizer protocol.

Number of subjects enrolled to date: 7 (chronic bronchitis)

Progress: Seven patients enrolled on this protocol without major difficulties. All adverse events were not related to the drug and all patients ameliorated while under follow-ups in clinic. This study was closed by PREMIER 18 March 1994.

Problems Encountered: One patient had resistant pathogen, non-drug related. rse Reactions: Adverse reactions included epigastric tenderness, rigid abdomen, rectal bleeding, throat erythema, UTI, kidney stone, GI bleed, and hypoxemia.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 93-51	**Status** Terminated
Title:	A Study to Investigate the Efficacy and Safety of Oral Valacyclovir (1000 mg or 500 mg, twice daily) Compared with Placebo in the Treatment of Recurrent Genital Herpes in Immunocompetent Patients		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Marshall A. Guill, MD, COL, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Dermatology		**Associate Investigators:** Roger V. Bruce, LTC, MC Mark G. Blaskis, MAJ, MC Susan Montieth, MT (ASCP)	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Terminated	

Study Objective: This is a company sponsored study to evaluate the efficacy and safety of valacyclovir to placebo in treating recurrent genital herpes in immunocompetent patients. By using the parent compound to acyclovir with less frequent dosing and giving to patients at home so as to start treatment within hours of symptom occurrence, it is hoped that greater efficacy may be found than has been true of earlier studies with acyclovir. It has three arms consisting of the two dose levels and placebo.

Technical Approach:

Number of subjects enrolled to date: 3

Progress: None

DETAIL SUMMARY SHEET

Date:	13 Jul 95	**Protocol** 95-32	**Status** Ongoing
Title:	A Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Effect of Cisplatin/Epinephrine Injectable Gel (Product MPI 5010) When Administered Intratumorally for Achievement of Treatment Goals in Recurrent or Refractory Squamous Cell Carcinoma of the Head and Neck.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Karen J. Bowen, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Stephen G. Oswald, COL, DO Kenneth I. Fink, LTC, MC Robert F. Krywicki, MAJ, MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To assess achievement of an identified improvable primary treatment goal selected for the most troublesome tumor in patients with recurrent or refractory squamous cell carcinoma of the head and neck.

Technical Approach: Randomized, double-blind, placebo controlled study of approximately 90 evaluable patients. Patients are stratified by total baseline tumor volume. Patients within each stratum are assigned in a 2:1 ratio to receive treatment with cisplatin/epinephrine gel (MPI 5010) or placebo gel in accordance with a predetermined randomization schedule.

Number of subjects enrolled: None.

Progress: None.

Problems encountered: Poor patient eligibility.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-1	**Status** Ongoing
Title:	GITS versus Core-Coated Nifedipine: Comparison of Efficacy Viq 24 hour Ambulatory Blood Pressure Monitoring		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): David A. Bookstaver, Pharm. D.		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine		**Associate Investigators:** Goldfinger, MP Cooper, EB Tam, CD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To determine the bioequivalence of Procardia-XL and Adalat-CC.

Technical Approach: Via a computerized search, 45 patients will be identified whose sole antihypertensive medication is Procardia-XL equally distributed among three dosing levels (30mg, 60mg, 90mg). This group of patients will have ambulatory blood pressure recordings obtained and then switched to the same dose of nifedipine in the Adalat-CC formulation. Three weeks following the switch, a second set of ambulatory blood pressure recording of the study patients will be obtained.

Progress: Enrolling patients on a regular basis.

Adverse reactions encountered: Acquisition of ambulatory blood pressure monitors took greater than a year. Internal Medicine Clinic staff illness absence has interferred with enrollment. It is difficult to find patients who will participate and meet study criteria especially since Procardia is only vasoactive medication.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-2	**Status** Terminated	
Title: A Phase I/II Study of SDZ PSC 833 with Doxorubicin, Vincristine, Cyclophosphamide, and Prednisone in Patients with Refractory or Relapsed Non-Hodgkin's Lymphoma			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Don W. Shaffer, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** MAJ Robert F. Krywicki,M.D. MAJ Karen Bowen, MD LTC Stephen Oswald, MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Terminated	

Study Objective: To evaluate the efficacy (i.e., complete response rate and duration, disease free and overall survival) of P-DVCP in refractory or relapsed intermediate or high grade non-Hodgkin's lymphoma.

Technical Approach: In Phase I of this study, patients will be assigned chronologically to five cohorts as defined by escalating doses of doxorubicin and vincristine. A minimum of four and a maximum of six patients will be accrued to each cohort. Once the cohort is assigned, the same regimen will be administered every 21 days for a maximum of 6 cycles.

Progress: None. Protocol terminated.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 94-13	**Status** Terminated
Title:	The Effect of Oral D-Sotalol on Mortality in Patients with Atherosclerotic Coronary Heart Disease and Left Ventricular Dysfunction		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Michael D. Lecce, MD, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Cardiology		**Associate Investigators:** LTC Farley Neasman, MC MAJ Matthew Smolin, MC MAJ James Wilkins, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Terminated	

Study Objective: To determine if oral d-Sotalol reduces total mortality in patients who had a myocardial infarction and have left ventricular dysfunction and to compare the safety and tolerance of d-Sotalol with placebo when administered long-term to patients with LV dysfunction.

Technical Approach: Eligible patients in the double-blind phase will be randomized to d-sotalol or placebo. Patients will receive oral d-sotalol 100mg or placebo BID for the first seven days. If tolerated, the dose will be increased to d-sotalol 200 mg or placebo BID for the remainder of the study. The study will be completed after all patients are enrolled and have been in the study for a minimum of 18 months. All randomized patients who discontinue study medication for any reason other than death will also be followed for the entire duration of the study.

Progress: None. Protocol terminated by manufacturer secondary to excess deaths in treatment ARM.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-35	**Status** Terminated	
Title: Elimination of Extrachromosomal DNA from Ovarian Cancer Patient's Tumor with Hydroxyurea Treatment			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Don W. Shaffer, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** MAJ Robert Krywicki, MC CPT Karen Bowen, MC LTC Stephen Oswald, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Terminated	

Study Objective: To re-explore the use of hydroxyurea in patients with refractory advanced ovarian cancer.

Technical Approach: Enroll patients with advanced, refractory ovarian cancer with malignant ascites who are requiring weekly paracenteses for comfort. Will remove the ascites and examine the fluid for number of tumor cells, the amount of extrachromosomal DNA in the tumor cells (as assessed by cytogenetics) (double minute DNA) or by molecular biology techniques.

Progress: No patients have been accrued. Protocol terminated.

DETAIL SUMMARY SHEET

Date:	13 Jul 95	**Protocol** 95-33	**Status** Ongoing
Title:	A Study to Evaluate the Effect of Cisplatin/Epinephrine Injectable Gel (Product MPI 5010) When Administered Intratumorally for Achievement of Treatment Goals in Accessible Tumors of any Histology. Matrix Protocol MP #403-93-2.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Karen J. Bowen, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Robert F. Kywicki, MAJ,MC Karen J. Bowen, MAJ, MC Stephen G. Oswald, COL,MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To assess achievement of an identified improvable primary treatment goal selected for the most troublesome tumor following up to 6 weekly treatments of MPI 5010 administered intratumorally in patinets with accessible tumors of various histologies.

Technical Approach: Open-label study of approximately 60-65 evaluable patients.

Number of subjects enrolled this reporting period: None.

Progress: None.

Problems encountered: Poor patient eligibility.

DETAIL SUMMARY SHEET

Date: 13 Jul 95	**Protocol** 94-95	**Status** Ongoing	
Title: The Effect of r-HuEPO in Patients with Small Cell Lung (SCLC): A Randomized, Double-Blind Placebo-Controlled Trial, N93-004			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Karen J. Bowen, MAJ, MC Stephen G. Oswald, COL,MC Kenneth Fink, LTC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To determine the effect of r-HuEPO vs placebo on tumor response in small cell lung cancer (SCLC) patients receiving therapy with VP-16 and cisplatin. The secondary objective of this study is to determine the effect of r-HuEPO on erythroid parameters in SCLC patients by measuring hemoglobin levels and transfusion requirements.

Technical Approach:

Number of subjects enrolled this reporting period: This institutiuon had one patient enrolled in this study who died due to progression of his disease.

Progress: None.

Problems encountered:

DETAIL SUMMARY SHEET

Date: 13 Jul 95	**Protocol** 95-1	**Status** Ongoing	
Title: A Natural History Study of Patients with Low Grade Lymphoid Malgancies Treated with Fludarabine			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Karen J. Bowen, MAJ, MC Stephen G. Oswald, COL,MC Raj R. Gupta, M.D. Kenneth Fink, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To perform a natural history study of patients with low-grade lymphoid malgancies treated with fludarabine. This study will also determine the degree and duration of immunodysfunction in patients with low-grade lymphoid maligancies treated with fludarabine.

Technical Approach: A data collecting schedule is outlined in appendix I of the protocol. Immunophenotyping (lymphocyte panel analysis) will be performed by flow cytometry employing a standard whole blood lysis procedure as described by the manufacturer of the lysis reagents.

Number of subjects enrolled this reporting period:

Progress: None.

Problems encountered:

DETAIL SUMMARY SHEET

Date:	13 Jul 95	Protocol	93-59	**Status**	Completed

Title:	The Use of Rapid Diagnostic Human Immunodeficiency Virus (HIV) Test Kits in a Field Environment (C)
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): David Craft, PhD, MAJ, MS	**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation	**Associate Investigators:** John R. Forney, MAJ, MS Linda E. Williams, SSG, USA
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Completed

Study Objective: To evaluate the sensitivity, specificity, precision and accuracy of commercially available rapid HIV test kits versus reference methods; the ease of use and interpretation of results; and the shelf life and practicality of storage in a harsh environment.

Technical Approach: Technical personnel will perform the blinded testing without prior training in order to simulate filed situations. Ease of use will be evaluated by technical personnel.

Number of subjects enrolled this reporting period:

Progress: All data collected. Study shows that rapid diagnostic kits for serological evaluation of HIV antibody and available and clinically accurate. These rapid kits can be deployed and used in a DEPMEDS facility. Results presented to the Society of Armed Forces Medical Laborataory Scientists.

Problems encountered:

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-41	**Status** Completed	
Title: Effectiveness of High Dose, Inhaled Triamcinolone Acetonide in Patients with Obstructive Airway Disease			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Carol R. Young, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** LTC Warren Whitlock, MC David Bookstaver, DAC Jorge Thompson, P.A. (FACT)	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Completed	

Study Objective: To assess the effectiveness of high dose, inhaled triamcinolone acetonide (Azmacort) in bronchodilator responsive obstructive lung disease in patients on inhaled bronchodilators who are on low-dose (two puffs four time per day) inhaled corticosteroids.

Technical Approach:

Progress: A total of 18 patients were enrolled without problems.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-62	**Status** Ongoing	
Title: A Randomized, Placebo-Controlled Trial of E5 Antiendotoxin Monoclonal Antibody in Patients with Severe Sepsis			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Ongoing	

Study Objective: To investigate the efficacy of E5 in the reduction of mortality in patients with severe sepsis due to documented/probable gram-negative infection.

Technical Approach: Patients that qualify for the study will be randomized to receive either E5 antiendotoxin monoclonal antibody or matching placebo at a 1:1 ratio according to a computer-generated randomization code provided by the sponsor.

Progress: A total of 2 patients have been enrolled. Both were evaluable.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 95-23	**Status** Ongoing	
Title: Phase III Randomized, Open-Label, Multicenter Study of Synercid (quinupristin/dalfopristin) plus Aztreonam vs Vancomycin plus Aztreonam in the Treatment of Gram-Positive Nosocomial Pneumonia			
Start Date: April 1995		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC MAJ William Browne, MC CPT Allen Borwne, MC Jorge Thompson, PA	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Ongoing	

Study Objective: To evaluate the clinical and bacteriological efficacy and safety of Synercid plus Aztreonam compared to Vancomycin plus Aztreonam for the treatment of hospitalized patients with nosocomial pneumonia due, at least in part, to a gram-positive pathogen(s).

Technical Approach: Guidelines will be followed by the Rhone-Poulenc Rorer Protocol JRV 306.

Progress: To date, no patients have been enrolled in this study at this site.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 95-2	**Status** Completed	
Title: Azithromycin in the Treatment of Hospitalized Patients wtih Community-Acquired Pneumonia. A Multicenter Open Trial			
Start Date: Dec 1994		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC MAJ Jesse Doers, MC Jorge Thompson, PA	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Completed	

Study Objective: To evaluate the safety and efficacy of azithromycin in the treatment of hospitalized patients with community-acquired pneumonia.

Technical Approach: Guidelines will be followed by the Pfizer Protocol No. 93-CE33-0625.

Progress: This institution has enrolled 11 patients and no adverse events were reported.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-85	**Status**	Closed
Title:	A Double-Blind, Randomized, Placebo-Control Multicenter Study to Investigate the Efficacy and Safety of GG167 Therapy in the Treatment of Influenza A and B Viral Infections.				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC Jorge Thompson, PA			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Ongoing			

Study Objective: To evaluate the efficacy of GG167 and the combination of inhaled and intranasal GG167 in the treatment of symptomatic influenza A and B viral infections.

Technical Approach: Patients that qualify for the study will be randomized to receive either E5 antiendotoxin monoclonal antibody or matching placebo at a 1:1 ratio according to a computer-generated randomization code provided by the sponsor.

Progress: A total of 2 patients have been enrolled. Both were evaluable.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-63	**Status** Ongoing	
Title: A Double-Blind, Parallel Group Evaluation of Salmeterol versus Placebo in the Treatment of Nocturnal Asthma			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Continue	

Study Objective: To characterize the efficacy of salmeterol, 42mg BID, when administered for 12 weeks to subjects with nocturnal asthmas; to characterize the safety profiles of salmeterol, 42mg BID, versus placebo BID, when administered over a 12 week period; and to evaluate the impact of salmeterol, 42mg, on quality of life dimensions (including sleeping) as compared to placebo BID in subjects with nocturnal asthma.

Technical Approach: Efficacy determinations will include symptom assessments, as well as daily peak flow measurements, and pulmonary function tests which will be performed Day 1 and after 4, 8, and 12 weeks of treatment. Subjects will be randomized into one of two strata: (1) subjects using theophylline, and (2) subject not using theophylline. Each subject will be evaluated during a two week basline period followed by a 12 week treatment.

Progress: A total of 5 patients have been enrolled.

Problems Encountered: Early withdrawals.

DETAIL SUMMARY SHEET

Date:	1 Sep 95 **Protocol** 94-84		**Status** completed
Title:	A Double Blind, Randomized, Placebo-Controlled Multicenter Study to Investigate the Efficacy and Safety of GG167 Therapy in the Prevention of Progression of Influenza A and B Viral Infections		
Start Date: Sep 94		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC Jorge Thompson, PA	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Completed	

Study Objective: To evaluate the efficacy of GG167 in the prevention of progression of influenza A and B viral infections (from asymptomataic to symptomatic). To assess the safety and pharmacokinetics of GG167 in the prevention of progression of influenza A and B viral infections (from asymptomatic to symptomatic). To determine route(s) of administration for Phase III protocol design.

Technical Approach: Treatment will follow Glaxo Protocol plan No. NAIA2006

Progress: A total of 4 patients enrolled at this site. No serious adverse events were reported.

Problems Encountered:

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-67	**Status** Closed	
Title: A Multicenter Open-Label Study to Evaluate the Safety and Efficacy of Levofloxacin in the Treatment of Bacterial Infections			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC CPT Michael Nelson, MC Jorge Thompson, PA	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Closed	

Study Objective: To evaluate the safety of intravenous levofloxacin in the treatment of bacterial infections of the respiratory tract, skin, and urinary tract due to susceptible organisms.

Technical Approach: Study population will consist of male or female subjects, 18 years of age or older, with clinical signs and symptoms of bacterial infections of the respiratory tract, skin, or urinary tract requiring intravenous antibiotic therapy.

Progress: None.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 94-70	**Status** Ongoing	
Title: A Multinational Multicenter, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Aerosolized Recombinant Pulmonary Disease Experiencing a Pulmonary Exacerbation.			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** MAJ Wayne Honeycutt, MC CPT Jesse Doers, MC Jorge Thompson, PA	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Ongoing	

Study Objective: To compare 90-day all-cause mortality; to compare the number of re-hospitalizations, the change in quality of life and the safety of 14 day Pulmozyme or placebo treatment at 90 days; and to compare all-cause mortality at 180 days.

Technical Approach:

Progress: A total of 21 patients enrolled.

Problems Encountered: None except for adverse events such as relapse of COPD exacerbation, 1 death. One patient had lung reduction done and now is ventilator dependent. No problems related to medication.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-81	**Status**	Completed
Title:	The Use of Rapid Diagnostic Hepatitis B (HEPB) Test Kits in a field Environment				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): David W. Craft, PhD, MAJ, MS			**Facility:** Eisenhower Army Medical Center		
Department/Service: Clinical Investigation			**Associate Investigators:** Steven E. Czerwinski, CPT(P), MS Ronald J. Figueroa, SSG(P), MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95 Completed		

Study Objective: To evaluate the sensitivity, specificity, precision and accuracy of commercially available rapid HEPB test kits versus reference methods; the ease of use and interpretation of results; and the shelf life and practicality of storage in a harsh environment.

Technical Approach: If needed, positive specimens will be re-confirmed by a reference laboratory. Each specimen will then be tested using three commercially available rapid test kits following the package insert testing procedure.

Number of patients enrolled this reporting period: None.

Progress: Continued screening for enrollment.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 95-18	**Status** Completed
Title:	The Effect of Videotaped Pre-Cardiac Catheterization Instruction and Personal Interview on the Anxiety and Knowledge Level of Pre-Cardiac Catheterization Patients.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Marie Price, CPT, AN		**Facility:** Eisenhower Army Medical Center	
Department/Service: Nursing		**Associate Investigators:** Debra Boykins, CPT, AN	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed	

Study Objective: To evaluate the effect of videotaped instruction supplemented with a personal interview on patient anxiety and knowledge in pre-cardiac catheterization patients.

Technical Approach: Patient satisfaction and patient behaviors demonstrated in the catheterization laboratory will be described. This random study is a single-group pre-test - post-test design with the group serving as its own control. patient anxiety and knowledge related to the cardiac catheterization instruction.

Progress: All data collected.

Number of Subjects Enrolled to Date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Mar 95	**Protocol** 95-15	**Status** Ongoing
Title:	The Relationship Between Nurses' Completion of a Pain Management Educational Program and Nurses' pain Documentation Behaviors.		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): LaDonna W. Howell, MAJ, AN		**Facility:** Eisenhower Army Medical Cener	
Department/Service: Nursing		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To determine if nurses who complete a pain management educational program demonstrate better assessment, documentation and evaluation of patient pain after completion of the pain management educational program as measured by the chart audit.

Technical Approach: The investigator will review charts on one or more surgical units within Dwight D. Eisenhower Army Medical Center. Following a two hour educational program on pain management, pain management documentation of course participants will be audited. Patients will not be identified.

Progress:

Number of Subjects Enrolled to Date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date: 9 Mar 95	**Protocol** 95-19	**Status** Ongoing	
Title: African-American Women's Knowledge of Hysterectomy			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Margaret Andrews, MAJ, AN		**Facility:** Eisenhower Army Medical Cener	
Department/Service: Nursing		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To describe what African-American women, aged 18 to 65 at a US Army Medical Center believe about hysterectomy.

Technical Approach: A convenience sample of 300 African-American women between the ages of 18 to 65 will be given questionnaires in the Family Practice, Surgical, Obstetrical, and Primary Care Clinics. The packets will be administered by the researcher and other nursing personnel at DDEAMC.

Progress: Submitted for Tri-Service Nursing Reearch Grant.

Number of Subjects Enrolled to Date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date: 13 Apr 95	**Protocol** 95-20	**Status** Ongoing	
Title: Impact of Telemedicine/Telenursing on Patients & Costs			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Loretta Schlachta, LTC, AN		**Facility:** Eisenhower Army Medical Cener	
Department/Service: Nursing		**Associate Investigators:** Lisa Bush, RN, MSN Richard McKnight, MAJ, MC Thomas E. Knuth, MAJ, MC Betsey S. Blakeslee, PH.D Placidia Clark, 1LT, AN Noel Poindexter, 1LT, AN Jack Horner, DAC Thomas Baker, 2LT Arlene Lowenstein, Ph.D Maribeth Johnson, Consultant	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To identify the impact of home based telenursing on patients' health outcomes and hospital utilization costs.

Technical Approach: The study is designed to answer the question "Will telenursing effect healthcare utiliation?" To answer the question, the latest low band width telemedicine technology in the form of desktop computers with a motion camera and appropriate medical instrumentation will be placed in sample patients' homes, and patients will be "visited" electronically by a telenurse.

Progress: Project not started, awaiting funding.

Number of Subjects Enrolled to Date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date: 9 Mar 95	**Protocol** 95-21	**Status** Ongoing	
Title: Efficacy of Clinical Case Management in the Military			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Frances Dee Anderson, LTC, AN		**Facility:** Eisenhower Army Medical Cener	
Department/Service: Nursing		**Associate Investigators:** Diane S. Brown, MSN Gloria L. Whitehurst, MSN Beverly Smith, BSN Mary Hardy, MA, Ph.D Susan I. Cowden Reinhart, BSN, MSN Joseph C. Kiser, BSN, MSN	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To determine and compare the efffects of managed care at a US Army Medical Center and an Army Community Hospital.

Technical Approach: Care will be directed by a nurse clinical case manager who manages the patient through both inpatient and outpatient setting, coordinating resources as appropriate.

Progress: This study was recently started - a Tri-Service Nursing Research Grant was awarded.

Number of Subjects Enrolled to Date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Mar 95	**Protocol**	94-82	**Status**	Ongoing
Title:	Identifying Process Variations Via Risk-Adjusted Outcome				
Start Date: Sep 94			**Est. Compl. Date:**		
Principal Investigator(s): Frances Dee Anderson, LTC, AN			**Facility:** Eisenhower Army Medical Cener		
Department/Service: Nursing			**Associate Investigators:** Kathryn J. Dolter, RN, MA Suzanne Bakken Henry, RN, MSN		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: The purpose of this study is to assess the validity of using risk-adjusted mortality as a screening mechanism to identify variations in practice impacting on quality of care. It will utilize DOD risk-adjusted mortality to identify medical centers having the potential for post-operative CABG patient care process variations, and then assess these medical centers' processes, specifically focusing on post-operative hemodynamic practices of nurses and physicians caring for these patients.

Technical Approach: The hymodynamic questionnaires are the instrument used in the Multicenter Pulmonary Artery Catheter Study and a blood pressure determination questionnaire. The organizational culture assessment questionnaire is the ICU Physician Questionnaire developed at Northwestern University.

Progress: This study was recently started - a Tri-Service Nursing Research Grant was awarded.

Number of Subjects Enrolled to Date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-55	**Status**	Ongoing
Title:	Perceptions of Women on Active Duty about Their Health Problems/Needs				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Mary Hardy, MAJ, AN		**Facility:** Eisenhower Army Medical Center			
Department/Service: Nursing		**Associate Investigators:** COL Joan Jack, AN			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Continue			

Study Objective:

Technical Approach: A convenience sample of all women on active duty in the Department of Defense in Region 3 (which includes Florida, Georgia and South Carolina) stationed at seven military installations will be asked to complete a questionnaire. A group assessment process will be utilized to gather data for the study. The investigator will personally administer the survey on the site of the installation at which subjects are assigned. Installation commanders will be contacted by phone and then with a follow-up letter and provided the purpose and methods of the research. They will be asked to contact staff within their commands who can identify all units with female soldiers and who would be helpful in facilitating the collection of data within these units. The units will then be contacted to arrange a date, time and place for the administration of the survey to the female soldiers within the unit.

Number of subjects enrolled for reporting period:

Progress: None.

DETAIL SUMMARY SHEET

Date:	1Sep 95	**Protocol**	94-61	**Status**	Terminated
Title:	Military Women's Perception of Sexual Harassment in the Military				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Dorothy Anderson, MAJ, AN		**Facility:** Eisenhower Army Medical Center			
Department/Service: Nursing		**Associate Investigators:**			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Terminated			

Study Objective: To ascertain female soldiers perception of sexual harassment in the military.

Technical Approach: A personally administered questionnaire will be used to elicit the perceptions and personal experiences of officer and enlisted female soldiers concerning sexual harassment in the military. Three groups of female service members from health care, military police, and signal occupation specialties will be administered the questionnaire.

Number of subjects enrolled for reporting period:

Progress: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-72	**Status**	Terminated
Title:	Propofol for Induction of Anesthesia: Comparison of Fentanyl and Alfentanil on Cardiovascular Response to Laryngoscopy and Tracheal Intubation				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Antonio De La Rosa, CPT, AN		**Facility:** Eisenhower Army Medical Center			
Department/Service: Nursing/Anesthesia		**Associate Investigators:**			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Terminated			

Study Objective: To describe the difference in the cardiovascular response to laryngoscopy and tracheal intubation when using fentanyl or alfentanil, following a standard adult propofol induction.

Technical Approach: The study will examine only standard adult propofol inductions, defined as persons years of age of older, categorized as American Society of Anesthesiologists I or II, receiving nonemergent anesthetic induction with the agent propofol at standard weight doses. The study will further be limited to attenuating effects of fentanyl and alfentanil only on the blood pressure and heart rate, and will not be generalizable to other opiates. Student nurse anesthetists will be performing the laryngoscopy and tracheal intubation during this study.

Number of subjects enrolled for reporting period:

Progress: Data collected on 54 patients and thesis presented.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-20	**Status:**	Closed
Title:	A Double-Blind Placebo Controlled, Parallel Study to Evaluate the Efficacy of Pepto-Bismol Liquid in the Treatment of Acute Diarrhea in Children Aged 3-6 Years				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Linda L. Fuqua, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Pediatrics			**Associate Investigators:** LTC Brenda Harper, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: This is a double-blind, placebo-controlled, parallel study to evaluate the efficacy of Pepto-Bismol liquid in the treatment of acute diarrhea in children aged 3-6 years.

Technical Approach: At the entry into the study, the degree of dehydration will be assessed clinically for each patient, and appropriate rehydration will be administered. Children with mild to moderate dehydration will be given non-rice ORS ad libitum over 4 to 6 hours. Children with severe dehydration will receive intravenous fluids as needed as well as ORS as tolerated ad libitum over 4 to 6 hours. Dosing with testing article will start after hydration has been completed. During the study, patients will receive a bland age-appropriate diet excluding lactose containing products. This will be followed by the child's regular diet as stools assume a normal consistency.

Progress: Study was never implemented.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-27	**Status:**	Closed
Title:	Assessment of Risk Factors for HIV Infection Among Active Duty U.S. Military Personnel with Documented Recent HIV-Antibody Seroconversion - Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Lynn Levine, PhD, MPH			**Facility:** Eisenhower Army Medical Center		
Department/Service: Preventive Medicine			**Associate Investigators:** William Challenger, RN		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To determine specific factors that are associated with becoming infected with the Human Immunodeficiency Virus (HIV).

Technical Approach: Participants will use a laptop computer with headphones. The computer will play a recorded version of each question in which the participant will answer on the keyboard. The survey will contain many items, including very personal questions about sexual and other behaviors.

Progress: This study has not started yet.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-43	**Status:**	Ongoing
Title:	The First Break Psychosis Study				
Start Date:	Sep 92		**Est. Compl. Date:**	May 95	
Principal Investigator(s): Elaine Correnti, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry & Neurology			**Associate Investigators:** Richard Borison, MD Manuel Casanova, MD Laura Davidson, PhD Bruce Diamond, MD Sahebarao P. Mohadik, MD Sukdeb Mukherjee, MD Thomas Ralston, LTC, MC Russell Scheffer, CPT, MC Neal Trent, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To determine whether specific biological abnormalities previously found in chronic schizophrenic patients are present at the beginning of the illness and, if so, to examine their relations to clinical characteristics of the illness; and to examine whether selected clinical, historical, and biological measures are predictive of short-term clinical outcome in patients experiencing their first episode of psychosis.

Technical Approach: Patients will undergo comprehensive psychiatric, neuropsychological, and neurological examinations at baseline, and blood samples will be taken for determination of RBC activities of specific enzymes and measurement of tritiated imipramine binding in platelets. A skin biopsy will be performed to develop fibroblast cell lines in culture and examine whether fibroblasts from patients show the abnormalities of growth and morphology noted in studies of chronic schizophrenic patients.

Subjects enrolled to date: 25

Progress: Continuing to enroll patients. Total to date is 34 with a goal of 50. Three papers published last year.

Problems Encountered: Technical problems when transferring MRI from optical discs at DDEAMC to electromagnetic tape.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-13	**Status:**	Ongoing
Title:	Dexamethasone Augmentation in the Treatment of Major Depression				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kerry Cleary, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry & Neurology			**Associate Investigators:** Russell Scheffer, CPT, MC Michael Sokol, MAJ, MC Joseph Sutcliffe, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: This is a double-blind, placebo controlled study to test the hypothesis of decreased latency of response to traditional antidepressant medication with a one time dose of Dexamethasone as adjunct on initiation of pharmacotherapy Double Blind Placebo Control.

Technical Approach:

Number of subjects enrolled: 12

Progress: Nine additional patients enrolled in the study since last approval. This marked increase in enrollment is secondary to improved communication between investigators and inpatient/outpatient staff of the Psychiatry Department.

Problems encountered: No adverse side effects noted from medications administered since last approval. (One of initial three patients has allergic reaction consisting of rash due to Prozac. Medication discontinued and patient was taken off study).

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-57	**Status:**	Completed
Title:	Controls for the Neurological Evaluation Scale and the Premorbid Adjustment Scale				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Russell Scheffer, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry & Neurology			**Associate Investigators:** Celso Bolet, COL, MC Elaine Correnti, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Completed		

Study Objective: This project will provide two groups of control subjects for clinical scales currently being utilized in the First Break Psychosis Study. This study has been proposed to obtain age and sex matched controls for our modification versions of the Neurological Evaluation Scale (Heinrichs and Buchanon 1989) and athe Premorbid Adjustment Scale (Canon-Spoor et al 1982).

Technical Approach: Fifty Active Duty subjects with no personal or family psychiatric history will be examined. These subjects will be obtained on a voluntary basis with input on timing of the evaluation determined after consultation with their command. Due to the current demographics of subjects in the FBPS, the AIT students at Ft. Gordon, GA represent an ideal group of age and sex matched controls.

Number of subjects enrolled: 50

Progress: All 50 normal control subjects have been obtained. Sixteen of the 50 psychiatric controls have been obtained.

Problems encountered:

DETAIL SUMMARY SHEET

Date:	9 Feb 95	**Protocol**	95-8	**Status:**	Ongoing
Title:	Attitudes, Experiences and Coping Strategies in Career Army Soldiers				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Elaine E. Correnti, MAJ, MC, DPN			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry			**Associate Investigators:** Mary Cruser, CPT, MC Laura Davidson, M.D.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To examine personality and environmental factors that enhance the well-being of women with ten years of experience in the military.

Technical Approach: A total of 400 subjects will be sampled. Half of the sample will be male and half will be female. The sample will consist of equal numbers of officers and enlisted soldiers. Subjects will be asked to complete a demographic and general information questionnaire.

Number of Subjects Enrolled to Date:

Progress: Fort Stewart, GA has been added as an additional site for this study. Questionnaires have been sent to perspective participants and now awaiting results.

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-47	**Status:**	Terminated
Title:	A Double-Blind, Placebo Controlled Exploratory Study of Sertraline in Adolescent Outpatients with Nondelusional Major Depressive Disorder.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kerry Cleary, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry			**Associate Investigators:** Lawrence M. Correnti, MAJ(P), MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** 1 Sep, Terminated		

Objective: To compare the efficacy of sertraline HC1 (SER) in major depressive disorder without psychotic features with placebo in a double blind fashion using a population of thirty 12 to 18 year old adolescent outpatients.

Technical Approach: Various structured interviews and instruments will be used to insure that DSM-III-R criteria are met. A washout period will precede randomization.

Number of subjects enrolled for the reporting period:

Progress: Unsuccessful screening for 8 months of subjects to enter protocol.

Problems encountered: Difficulty with subject recruitment.

DETAIL SUMMARY SHEET

Date:	9 Feb 95	**Protocol**	95-22	**Status:**	Ongoing
Title:	Psychiatric Symptom Correlation with Continuous Performance Test Performance.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kerry Cleary, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry/Neurology			**Associate Investigators:** Daphne Albright, Ph.D.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To investigate if there is a correlation between depressed mood, anxiety, and disruptive behavior with performance on the computerized Continuous Performance Test (CPT).

Technical Approach: Fifty children between the ages of 6 and 17 will be referred to the Child, Adolescent, and Family Psychiatry Service for evaluation and/or treatment. Actual subject selection will be determined largely by parental consent..

Number of Subjects Enrolled to Date: Fifty-four.

Progress: All data collected, will now begin statistical analysis.

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	11 May 95	**Protocol**	95-30	**Status:**	Ongoing
Title:	The Efficacy of Sertraline in Chronic Pain Management				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Michael L. Cohen, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Psychiatry		**Associate Investigators:** Rance W. Humphreys, CPT, MC Charles B. Davis, CPT, MC Darcelle M.Delrie, LTC, MC Benjamin W. Page, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To evaluate the efficacy of Sertraline in the treatment of patients with a variety of chronic pain syndromes..

Technical Approach: Participants will be randomized to Sertraline or placebo for six weeks. Patients will come in for visits in weeks 1,4,7, and 10 of the study. Visits will last up to 30 minutes during which time the patient will be given the next week's amount of medication, and be asked questions concerning their thoughts, feelings and pain symptoms, as well as possible side effects they may be experiencing from the medication.

Number of Subjects Enrolled to Date:

Progress: Study recently implemented since receipt of drug

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Feb 95	**Protocol**	95-12	**Status:**	Ongoing
Title:	Influence of Parenteral Progesterone Administration on the Prevalence and Severity of Mastodynia in Active Duty Servicewomen: A Multi-institutional Cross-Sectional Study.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): CPT Meredyth Munns, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: OB/GYN			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To provide a better understanding on the causes of mastodynia.

Technical Approach: This study proposes to poll a large number of servicewomen. A questionnaire will be used to document the presence and measure the severity of breast pain. A cross-sectional method will be used to compare the frequency of mastodynia between women receiving long-term progesterone supplementation (for contraception) and those not receiving supplementation.

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	90-1	**Status:**	Terminated
Title:	Technetium 99m Antimony Trisulfide Colloid for Investigation of Lymphatic Drainage				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Stephen G. Oswald, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Radiology/Nuclear Medicine			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Terminated		

Study Objective: To provide a radiopharmaceutical whereby lymphatic drainage may be characterized.

Technical Approach: Intradermal injection of radiolabeled colloidal particles with serial gamma camera images to evaluate lymphatic drainage.

Number of subjects enrolled to date: 4

Progress: This radiopharmaceutical has been unavailable for several years, and there is no indication that it will become available in the near future. Therefore, request protocol be closed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	90-36	**Status:**	Ongoing
Title:	Treatment of Internal Contamination by Plutonium and Other Transuranic Elements with Two Investigational New Drugs (Ca-DTPA and Zn-DTPA)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert J. Kaminski, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Radiology/Nuclear Medicine			**Associate Investigators:** Stephen G. Oswald, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: The principal objective of this protocol is to obtain approval from the IRC to use Ca-DTPA and Zn-DTPA for the treatment of patients at Eisenhower Army Medical Center who are internally contaminated with plutonium or other transuranic elements.

Progress: This is not an investigational study. Protocol has enabled EAMC to obtain Ca-DTPA and Zn-DTPA from the Oak Ridge Institute for Science and Education for the emergency treatment of individuals who are internally contaminated with plutonium or other transuranic elements. No patients were treated this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-39	**Status:**	Closed
Title:	Adrenal Imaging with 131-Iodine-6-Beta-Iodomethyl-Norcholesterol (NP-59)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Stephen G. Oswald, LTC, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Radiology/Nuclear Medicine		**Associate Investigators:** Robert J. Kaminski, LTC, MC Daryl S. Moyer, CPT, MS			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed			

Study Objective: To provide a mechanism whereby NP-59 is available for correlative adrenal imaging for patients with biochemically established ACTH-independent Cushing's syndrome, primary aldosteronism, or androgen excess states as well as characterization of the functional status of euadrenal masses.

Technical Approach: Intravenous injection of a radiopharmaceutical (NP-59) with subsequent gamma camera imaging.

Progress: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-28	**Status:**	Closed
Title:	Magnetic Resonance Imaging to Optimally Find and Accurately Define the Extent of Malignant Breast Lesions				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): George P. Forsyth, M.D.			**Facility:** Eisenhower Army Medical Center		
Department/Service: Radiology			**Associate Investigators:** LTC Thomas Ralston, MC MAJ Sandra Pupa, MC MAJ Noel Haskins, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To determine if magnetic resonance imaging (MRI) of the breast can provide a better means for detection of breast neoplasms (malignant tumors) than physical examination and/or plain film mammography. The purpose of this study is to also to determine how best to distinguish non-cancerous lesions from cancerous lesions within the breast.

Technical Approach: Perform magnetic resonance mammography on women with lesions that require biopsy. Such masses would be found by physical examination or detected by plain film mammograms. Only the single breast containing the lesion to be biopsied will be scanned. The results of this examination will be correlated with previous exams (mammography, ultrasound, etc.) and with pathologic specimens obtained from the breast biopsy.

Progress: Study not implented due to lack of funding.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-48	**Status:**	Ongoing
Title:	Pelvic Pathology: Prospective Comparison of Computed Tomography, Ultrasound, and Magnetic Resonance Imaging				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): George P. Forsyth, M.D.		**Facility:** Eisenhower Army Medical Center			
Department/Service: Radiology		**Associate Investigators:** Stephen Oswald, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To demonstrate the effectiveness of 5th generation magnetic resonance imaging (MRI) versus computerized tomography (CT) and ultrasonography (US) and to determine if advances in magnetic resonance image quality have allowed MRI to surpass CT and US in the detection and definition of pelvic pathology in women.

Technical Approach: This study will evaluate female patients who meet clinical criteria for pelvic surgery. Imaging of the pelvis will be performed with three modalities (MRI, CT, US) and findings will be correlated with the histologic diagnosis. Oral barium contrast will be used in combination with intravenous gadolinium contrast to enhance pelvic organs during the high speed image acquisition now possible with 5th generation MRI equipment.

Progress: This study has not been implemented due to lack of funding.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	95-9	**Status:**	Ongoing
Title:	Creation of a Prostate Cancer Data Base for the Center for Prostate Disease Research (CPDR)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Donald J. Lewis, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To retrospectively collect data on prostate cancer patients and aid in developing a data base on these patients at Walter Reed Army Medical Center, Center for Porstate Disease Research (CPCR).

Technical Approach: It is estimated that it will take 1-2 years to have a sound database, and that other associated military facilities will contribute to this database. The data collected and stored in the CPDR database is information that is normally collected on a newly diagnosed prostate cancer patient from initial diagnosis to treatment to follow-up care.

Number of Subjects Enrolled to Date: None

Progress: Presently recruiting patients.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	90-32	**Status:**	Closed
Title:	Training General Surgery Residents Utilizing Goat and Pig Models				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): William C. Calton, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Clinical Investigation			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To allow the practicing and refinement of surgical approaches and techniques on animal models prior to performing the same procedure in the human.

Progress: Two major Southeast regional courses were conducted to successfully train in new laparoscopic hernia and colorectal surgery to 38 students and weekly training to residents and staff. Also, nursing anesthesia students were trained on field Army anesthesia machines during these sessions. Operating room nurses were trained on laproscopic techniques and a multidisciplined laboratory training session for gynecologists and general surgeons in gastro/enterology laparascopy.

DETAIL SUMMARY SHEET

Date:	11 May 95	**Protocol**	95-29	**Status:**	Ongoing
Title:	A Double-Blind Placebo Controlled Clinical Trial Comparing the Efficacy and Safety of Prolonged Out-Patient Enoxaparin and Placebo Therapies in the Prevention of Venus Thromboembolic Disease in Patients Undergoing Elective Primary Hip or Knee Replacement.				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Joseph M. Erpelding, LTC, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/Orthopedics		**Associate Investigators:** Wallace B. Brucker, MAJ, MC Nicholas J. Yokan, MAJ, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To compare the efficacy and safety of extended, once-daily enoxaparin, 40 milligrams, and placebo treatment for the prevention of venous thromboembolic disease in patients undergoing elective, primary total hip or total knee replacement surgery.

Technical Approach: All patients will receive initially 7 to 10 days of subcutaneously administered enoxaparin, 30 mg twice daily treatment followed by once daily enoxaparin or placebo injections for a total treatment duration of 28 days.

Number of subjects enrolled this reporting period: Eleven.

Progress: Continuing patient enrollment.

Problems encountered: Three patients refused end of treatment venograms.

DETAIL SUMMARY SHEET

Date:	11 May 95	**Protocol**	95-31	**Status:**	Ongoing
Title:	Does Arginine Promote Wound Healing In Chronic Foot Ulcers?				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Anthony B. Cresci, MAJ, DPM			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopedics			**Associate Investigators:** Gail Cresci, T.D., C.N.S.D. Robert Martindale, M.D., Ph.D.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To determine the effects of supplemental oral intake of the non-essential amino acid arginine on wound healing.

Technical Approach: Patients with chronic foot ulcers will be randomized utilizing the last digit of their social security number to receive either oral dietary supplement of 30 grams arginine per day or a placebo.

Number of subjects enrolled this reporting period:

Progress: Study recently implemented since receipt of drug.

Problems encountered:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-4	**Status:**	Closed
Title:	The effect of pentoxifyline vs allopurinol on sigmoid mucosal ischemia during abdominal aortic surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): William C. Calton, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC Manuel F. Ramirez, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: This study will make considerable use of a new noninvasive technique to measure the adequacy of tissue oxygenation called tonometry.

Technical Approach: Tonometry relies upon the fact that CO_2 is freely permeable between the lumen, luminal fluid and superficial layer of the mucosa. By measuring CO_2 in the luminal fluid and simultaneously measuring arterial blood gases, mucosal pH can be calculated using the Henderson-Hasselbalch equation. The validity and safety of this technique has now been substantiated in several studies.

Progress: Project on hold due to lack of technical assistance and equipment limitations. Protocol will continue when research nurse is available.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	85-5	**Status:**	Closed
Title:	Advanced Trauma Life Support Course				
Start Date: Jan 85			**Est. Compl. Date:**		
Principal Investigator(s): Paul Lepage, MAJ, MC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

Technical Approach: The advanced trauma life support course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-81	**Status:**	Closed
Title:	Evaluation of the Current Routine Post-Op Feeding Regimens				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): M. Brian Harkins, CPT MC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To determine if patients are able to tolerate a regular diet rather than clear liquids as their first P.O. intake following intraabdoinal surgery.

Technical Approach: Randomized patients to alternate diets.

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-13	**Status:**	Closed
Title:	The Efffect of IV Pentoxifylline on Endotoxin Mediated Small Bowel Mucosal Ischemia Using the Pig Model				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): William C. Calton, Jr., CPT MC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC Michael P. Byrne, LTC, MC David Turgeon, PhD, MAJ, MS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To determine if patients are able to tolerate a regular diet rather than clear liquids as theiur first P.O. intake following intraabdoinal surgery.

Technical Approach:

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-26	**Status:**	Closed
Title:	The Effects of Somatostatin Analog (Octreotide Acetate) on Wound Healing in the Mouse Model				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert G. Martindale, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Donald E. Sutherland, PhD, MAJ, MC William Calton, Jr, CPT, MC Sam Miller, CPT, MS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To determine if the somatostatin analog affects wound healing.

Technical Approach:

Progress: Techniques for PTFE implantation have been perfected.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-27	**Status:**	Closed
Title:	Natural History of Free Gallstones Within the Peritoneum in a Rabbit Model and Mouse Model				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Roy Workman, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/General Surgery		**Associate Investigators:** Michael Byrne, LTC, MC Robert G. Martindale, MAJ, MC Thomas R. Gadacz, MD			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed			

Study Objective: To determine the physiologic response to free gallstones within the peritoneum in the rabgit and mouse models.

Technical Approach:

Progress: Initial surgery has been completed and waitaing for specific times to gather data on acute inflammatory changes associated with spillage of gallstones using histologic, microbiologic, and immunologic procedures.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-52	**Status:**	Closed
Title:	Laparoscopic Appendectomy vs Standard Appendectomy				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Thomas Taylor, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/General Surgery			**Associate Investigators:** Victor L. Modesto, MAJ, MC Paul A. LePage, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To compare hospital stay, amount of post-operative pain medications, amount of post-operative complications such as wound infection and abscess formation, and the percentage of false positives to that of open appendectomy. We also wish to become proficient in the art of laparoscopic appendectomy.

Technical Approach: Open appendectomy will be performed in the standard fashion utilizing a Rockey Davis incision. An extension of this incision may be utilized as deemed necessary by the senior surgeon performing the case. All open appendectomies will undergo irrigation of the pelvis in the reverse trendelenburg position.

Progress: Project completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-4	**Status:**	Closed
Title:	The Effect of Early Enteral Feeding on Patients Undergoing Abdominal Aortic Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): William C. Calton, Jr., CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC Donald E. Sutherland, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To evaluate the effect of early enteral feeding an outcome, nutritional parameters and wound healing in patiaents undergoing abdominal aortic surgery.

Technical Approach:

Progress: Ten patients enrolled. Data completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-4	**Status:**	Closed
Title:	The Effect of Early Enteral Feeding on Patients Undergoing Abdominal Aortic Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): William C. Calton, Jr., CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC Donald E. Sutherland, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To evaluate the effect of early enteral feeding an outcome, nutritional parameters and wound healing in patiaents undergoing abdominal aortic surgery.

Technical Approach:

Progress: Ten patients enrolled. Data completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-35	**Status:**	Closed
Title:	Effects of Somaatostatin Analog (Octreotide Acetate) on Wound Healing in Bowel and Gastric Anastomosis in the Rat Model				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Samuel K. Miller, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC Donald E. Sutherland, MAJ, MC William Calton, Jr, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To determine the efffects of somatostatin analog (Octreotide acetate) on bowel and gastric anastomosis.

Technical Approach:

Progress: Two sets of rats (35 in first; 40 in second) show trend but no significant progress. Study completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-61	**Status:**	Closed
Title:	The Effect of Vitamin A on the Steroid Induced Defect in Wound Healing: A Time Course Study in Mice				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Patricia S. Greatorex, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC Donald E. Sutherland, MAJ, MC Peter M. Barcia, COL, MC Steven Tobias, MAJ, DVM		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To evaluate the potential beneficial effect of Vitamin A in reversing the detrimental effect steroids have on wound healing, examine in chronological sequence the inhibitory effect of corticosteroids on wound healing with and without the addition of Vitamin A, and create a time response curve that will demonstrate when steroids have their peak inhibitory effect and what role Vitamin A has in this time sequence.

Technical Approach:

Progress: Protocol completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-63	**Status:**	Closed
Title:	The Adverse Effects of Octreotide on Wound Healing in Rats Study in Mice				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Brad E. Waddell, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC Cheuk Y. Hong, CPT, MC Steven Tobias, MAJ, DVM		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To determine the natuare and extent of octreotide's adverse effects on wound healing.

Technical Approach:

Progress: Protocol completed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-37	**Status:**	Closed
Title:	Translocation Bacteremia from the Lung Caused by Volume Ventilation in Sus Scrofa				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Thomas B. Taylor, Jr. CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** David Craft, PhD, MAJ, MSC Arthur Wozniak, PhD, LTC, MC Thomas Knuth, MAJ, MC Karon B. Mansell, BS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: The objective will be to determine whether volume ventilation has an effect on bacterial translocation in the porcine lung.

Technical Approach:

Progress: Electron microscopy and light microscopy has ben concluded.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-43	**Status:**	Closed
Title:	Gut Colonization as a Predictor of Nosocomial ICU Infections				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Thomas E. Knuth, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Ted Newton, MAJ, AN		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To document the presence of pathogenic organisms in gastric aspirates; to determine the relationship of these organisms to subsequent nosocomial infections.

Technical Approach:

Progress: Study closed.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	95-34	**Status:**	Ongoing
Title:	Comparative Study of the Clinical Efficacy of two Dosing Regimens of Eulexin				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Richard W. Knight, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Donald Lewis, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To compare the clinical effectiveness of a new dosing regimen for administering flutamide to the currently indicated dosing regimen.

Technical Approach: This is a Phase IV, multicenter trial in which 400 evaluable patients with de novo Stage M, metastatic prostate cancer will be randomized to a group. Patients will enter the study no later than two weeks after the screening visit and will be randomly assigned to a treatment group at Time 0. Flutamide therapy will be initiated the same day as either surgical or medical castration, and continued for three months.

Number of subjects enrolled this reporting period: Two patients enrolled, one recently completed study.

Progress: Recruitment of patients continues.

Problems encountered: None.

DETAIL SUMMARY SHEET

Date:	21 Sep 95	**Protocol**	95-45	**Status:**	Ongoing
Title:	Hemodynamic and Arterial Blood Gas Changes from Preperitoneal Carbon Dioxide Insufflation: Laparoscopic Preperitonea Dissectionin a porcine Model (Sus Scrofus).				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Michael W. Blaney, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** William Calton, MAJ, MC Samuel K. Miller, CPT, MC Manuel Ramirez, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To evaluate the physiologic effects that preperitoneal pneumoperitoneum has on cardiovascular hemodynamics, ventilatory mechanics, and arterial blood gas values..

Technical Approach: To perform the standard preperitoneal hernia repair on a pig model while monitoring hemodynamic parameters using a swan ganz catheter, as well as an arterial catheter to monitor blood pressure and blood gas values.

Number of subjects enrolled this period:

Progress: All data collected, statistical analysis in progress.

Problems encountered:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-42	**Status:**	Ongoing
Title:	Mechanical Peritoneal Retraction Laparoscopic Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): David E. Rivera, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Manuel F. Ramirez, MD, LTC, MC General Surgery Service		
Key Words:			Medical Monitor: Richard C. Traugott, MD, COL, MC		
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95 Continue		

Objective: To demonstrate whether the Laparolift System provides equivalent or better exposure than conventional pneumoperitoneum.

Technical Approach:

Number of subjects enrolled for reporting period: None

Progress: Progress is help waiting for MEDCASE approval for purchase of laprolift device.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-65	**Status:**	Ongoing
Title:	The Use of 1% Lidocaine With/Without Epinephrine in Breast Biopsy				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Samuel Miller, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** Darren Chapman, CPT, MC Scott Needham, CPT, MC Paul A. Lepage, MAJ, VC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95 Continue			

Objective: To determine complication rates in breast biopsies as influenced by the use of local anesthetic.

Technical Approach:

Number of subjects enrolled for reporting period: 200

Progress: Protocol still in data collection phase.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-14	**Status:**	Complete
Title:	A Randomized, Open-Label, Parallel Group Comparison of the Safety and Efficacy of Lovenox (Enoxaparin) Injection vs Adjusted Dose Coumadin (Warfarin) in the Prevention of Thromboembolic Disease Following Hip Replacement Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Joseph M. Erpelding, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** CPT Paul Benfanti, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Complete		

Objective: To evaluate the safety and efficacy of Lovenox Injection versus adjusted dose Coumadin in the prevention of clinically significant thromboembolic disease following elective total hip replacement during hospitalization and to determine the medium term incidence (three months post-hospital discharge) of morbidity and mortality resulting from thromboembolic disease following elective total hip replacement surgery in patients treated with Lovenox injection versus adjusted dose Coumadin.

Technical Approach: This protocol study is divided into two phases; an inpatient period following surgery, not to exceed 14 days, and an outpatient followup period of three months. When the surgeon is satisfied that hemostasis has been achieved, and within 24 hours post-operatively, patients will begin their randomly assigned treatment of either Lovenox injection, 30 mg BID, or adjusted dose Coumadin until hospital discharge, but not to exceed a maximum of fourteen days. All patients will return to the investigator for followup examination at approximately six and twelve weeks post-hospital discharge.

Number of subjects enrolled for reporting period:

Progress: Completed 25 patients.

Adverse Reactions: One patient developed post-op hematoma and was withdrawn from study.

Problems Encountered: None.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-32	**Status:**	Terminated
Title:	Segregation and Sequence Analysis of a Candidate Breast Cancer Gene in Affected Families				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert S. Thomas, Jr., MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** Nurul Sarkan, MD, MCG Terry Spinkle, MD, MCG Francis Chandler, MD, MCG Aquan Kripamoy, MD, MCG Li Yin-Xwing, MD, MCG			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Terminated			

Objective: To evaluate the exact location of the CNP gene in relation to the other well studied closely linked markers.

Technical Approach: Patient participation is limited to donating tissue being removed for clinical indications. If positive cases are found, family members will be invited to donate blood by venipuncture.

Number of subjects enrolled for reporting period: None.

Progress: None.

Problems encountered: Study was never initiated due to lack of funding.

Date:	1 Sep 95	**Protocol**	94-42	**Status:**	Complete
Title:	A Randomized Study to Compare the Safety and Efficacy of Various User-Convenient Dosing Regimens of Procrit (Epoetin Alfa) in Subjects Undergoing Major Orthopaedic Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Joseph Erpelding, LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** MAJ John Kragh, MC CPT Joseph Legan, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95 Complete		

Objective: To compare the safety and efficacy of various user-convenient dosing regimens of PROCRIT in subjects undergoing major orthopaedic surgery (hip or knee replacement) to determine if a more user-convenient dosing regimen with lower total doses of PROCRIT produces an erythropoietic response comparable to PROCRIT 300 U/kg x 15 doses.

Technical Approach: One hundred thirty subjects scheduled for major orthopaedic surgery involving hip or knee replacement will be enrolled in this study. Subjects must be unwilling or unable to participate in an autologous blood predeposit program. As subject qualify for the study, they will be assigned to one of four treatment groups. All subjects will receive an oral iron supplement provided by R.W. Johnson PRI, throughout the course of treatment, starting at least on the first day of study medication. Safety evaluations will be made by clinical laboratory tests, vital sign measurements, and by the incidence and severity of adverse events. In addition, a complete physical examination will be performed prestudy and upon completion.

Number of subjects enrolled for reporting period: 5

Progress: Study Completed.

Problems Encountered:

Date:	1 Sep 95	Protocol	94-44	Status:	Ongoing
Title:	Kinematic Effect of Twisting on Anterior Cruciate Ligament Patellar Bone-Tendon-Bone Grafts in Anterior Cruciate Ligament Reconstruction in Cadaveric Knees				
Start Date:			Est. Compl. Date:		
Principal Investigator(s): Francis Moll, CPT, MC			Facility: Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			Associate Investigators: CPT Richard Pope, MC MAJ Dean Taylor, MC COL Dennis Runyan, DE		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results: Sep 95, Continue		

Objective: To evaluate the possible beneficial and/or deleterious effect graft rotation has on the kinematics of the knee in ACL reconstruction.

Technical Approach: An in vitro study utilizing a previously described cadaver model for knee kinematics will examine the effect of twist on a patellar BIB graft in ACL reconstruction. A fresh frozen cadaver lower extremity with no recorded or demonstrable musculoskeletal disease will be used as a knee model for ACL reconstruction.

Number of subjects enrolled for reporting period:

Progress: Alteration of mechanical testing. Initial trial tests showed flaw with one aspect of experimental design.

Problems Encountered: Inability to use tensiometer. Strain gauges with a twisted ligament will rectify this problem using another testing tool - K.T. 2000.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-60	**Status:**	Ongoing

Title:	The Biochemistry and Physiology of Wound Healing in Association with Synthetic Materials Used for Temporary Closure of Abdominal Wall in the Rat Model

Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Sidney R. Steinberg, COL, MC R. Martindale, M.D., PhD, MCG	**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery	**Associate Investigators:** X.X. Gao, PhD, MCG T.R. Howdieshell, MD, MCG COL Manual Ramirez, MC MAJ David Craft, MS M. Hawkins, MD, MCG MAJ Steven Tobias, MS, DVM Norma Best, MS
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Objective: To evaluate the effectiveness and utility of synthetic materials in emergent abdominal wall closure, and to determine and design the optimal material to be used for emergent closures.

Technical Approach: This protocol will also attempt to address the mechanisms of altered wound healing noted when using synthetic material. Post-operative pain will be monitored by behavioral criteria with analgesics administered as required.

Number of subjects enrolled for reporting period:

Progress: One major set of studies done. Early mortality felt to be secondary to URI/virus in animals last summer.

Date:	1 Sep 95	Protocol	94-64	Status:	Closed
Title:	The Application of Advanced Telemedicine and Related Off-the-Shelf Medical Technology to Improve Overall Healthcare Delivery for Deployed Military Women				
Start Date:			Est. Compl. Date:		
Principal Investigator(s): Thomas E. Knuth, MAJ, MC			Facility: Eisenhower Army Medical Center		
Department/Service: Surgery			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results: Sep 95, Closed		

Objective: To demonstrate use of advanced medical and communications technologies to project medical subspecialty expertise to remote locations; to define technologies and connectivity required to operate telemedicine from remote locations; and to determine physician and patient acceptance of advanced technologies.

Technical Approach: Advanced digital compression-decompression devices and connectivity links and emphasize economical, readily available commercial phone lines. After each consultation, medical care providers from both sites and the patient will be asked to fill out satisfaction surveys which will be used to assess acceptance of the technology as well as psychological impact, especially relevant to deployment of women.

Number of subjects enrolled for reporting period:

Progress: None.

Date:	1 Sep 95	**Protocol**	94-66	**Status:**	Ongoing
Title:	Treatment of Thoracolumbar Burst Fractures. A Prospective, Randomized Trial.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Alfred E. Geissele, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** LTC Joseph M. Erpelding, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Objective: To compare the outcomes of non-operative versus operative treatment of thoracolumbar burst fractures. This study will also evaluate and compare differences in clinical, radiographic, and functional outcomes between the two treatments.

Technical Approach: Patients will be enrolled and randomized without regard to loss of anterior vertebral body height, segmental kyphosis, or degree of canal compromise. Prior to entry, patients will undergo AP and lateral radiographs of the thoracolumbar spine and a CT evaluation of the canal at the level of the fracture. A history of premorbid back pain or injuries will be asked for as well as a pain drawing and a visual analogue pain rating, a Denis pain and work scale, and an Oswestry Disability Questionnaire.

Number of subjects enrolled for reporting period: None.

Progress: None.

Date:	1 Sep 95	Protocol	94-90	Status:	Ongoing
Title:	The Epidemiology of Youth Soccor Injuries				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): John Kragh, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** Dean Taylor, MAJ,, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Objective: The understanding of yough soccer injuries aids in prevention. There remain several contaroversial areas concerning youth soccer. This study design will be a prospective case control at one location over several years. There will be no medication utilized for this study. The type of population served will be the participants in the Augusta Arsenal Spring Shootout (AASS)

Technical Approach:

Number of subjects enrolled for reporting period: 1500

Progress: One year of data collected.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-91	**Status:**	Ongoing
Title:	Comparison of Rotational Stability of Oblique Fibula Fractures Fixed with Bioabsorbable Screws Compared to Stainless Steel Screws in the Human Malleolus				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Joseph J. Legan, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopaedics			**Associate Investigators:** David Brown,CPT, MC Joseph Erpelding, LTC, MC Dennis Runyan, COL, DE		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Objective: To compare the rotational stability of distal afibula fixed with 4.5 MM PGA polyglycolic acid screws (Bioscience Ltd, Tampere, Finland) versus 3.5mm (Synthes, USA) stainless steel cortical screws in cortical bone.

Technical Approach: This will be an in-vitro study utilizing matched cadaver fibulas. Results will be recorded in newtons-meters. This manner to test rotational stability of fixed fractures hasa been previously substantiated.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-92	**Status:**	Completed
Title:	Pull Out Strength of Absorbable versus Stainless Steel Screws in the Human Medial Malleolus				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Joseph J. Legan, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/Orthopaedics		**Associate Investigators:** David Brown,CPT, MC Joseph Erpelding, LTC, MC Dennis Runyan, COL, DE			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, completed			

Objective: To compare the pull out strength of 4.5 mm PGA polyglycolic acid screws (Bioscience Ltd, Tampere, Finland) to 4 mm (Synthes, USA) stainless steel cancellous screws in cancellous bone.

Technical Approach: This will be an in vitro study utilizing matched cadaver medial malleoli. In each set one screw of each type will be placed in a medial malleolus according to standard orthopaedic (AO) technique. Manufacturer's guidelines will be followed for sizing of drill bit, tap and screw driver.

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-93	**Status:**	Ongoing
Title:	Pull Out Strength of Uncemented Aetabula: A Comparison of Press Fit versus Acetabula Fixed with Bioabsorbable Screws				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Joseph J. Legan, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/Orthopaedics		**Associate Investigators:** David Brown,CPT, MC Joseph Erpelding, LTC, MC Dennis Runyan, COL, DE			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Ongoing			

Objective: To compare the pull out strength of press fit acatabular cups (Howmedica USA) to those same cups fixed with 4.5mm polyglycolic acid screws (Bioscience Ltd, Tampere, Finland) in adult cadeveric pelves.

Technical Approach: This will be an in vitro study utilizing cadaver pelves.

Number of subjects enrolled for reporting period:

Progress:

Date:	1 Sep 95	Protocol	94-69	Status:	Closed
Title:	Migration of Prolene Mesh Following Laparoscopic Preperitoneal Hernia Repair.				
Start Date:		Est. Compl. Date:			
Principal Investigator(s): Sidney Steinberg, COL, MC		Facility: Eisenhower Army Medical Center			
Department/Service: Surgery		Associate Investigators: Lisa Bromberger, RN CPT Samuel Miller, MC Dr. Robert Martindale, MCG MAJ Noel Haskins, MC			
Key Words:					
Accumulative MEDCASE Cost:		Periodic Review Results: Sep 95, Closed			

Objective: To determine how much and when the prolene mesh migrates from the abdominal wall following a laparoscopic preperitoneal hernia repair.

Technical Approach: The study will be such that during the preperitoneal hernia repair the prolene mesh, with a fine radiopaque suture material woven into the perimeter of the material, will be placed in the standard fashion. Immediately upon complete of the hernia repair, while the patient is still under anesthesia, a flat plate of the abdomen will be taken. The x-ray will then be read by the operating surgeon, principal investigator, and the faculty radiologist to evaluate location and position of marlex mesh. At three months the patient will be asked to return to the hospital for one additional abdominal x-ray in the supine position. Those x-rays will then be compared for migration of mesh. The x-ray will be coned down as much as possible to the area of interest.

Number of subjects enrolled for reporting period:

Progress:

Date:	09 Sep 954	Protocol	94-71	Status:	Closed
Title:	The Effect of Intraoperative Hip Position on Maintenance of Lumbar Lordosis.				
Start Date:		Est. Compl. Date:			
Principal Investigator(s): Paul L. Benfanti, CPT, MC		Facility: Eisenhower Army Medical Center			
Department/Service: Surgery/Orthopaedics		Associate Investigators: MAJ Alfred E. Geissele, MC			
Key Words:					
Accumulative MEDCASE Cost:		Periodic Review Results: Sep 95, Closed			

Objective: To determine the effect of hip position on maintenance of lumbar lordosis during positioning on the Wilson frame.

Technical Approach: There will be three limbs to this study. The first is retrospective and radiographic data review on patients undergoing lumbar surgery. The second limb will involve obtaining intraoperative x-rays on patients undergoing lumbar discectomy or fusion on the Wilson frame with their hips in the flexed and extended position. Normally two localizing x-rays are obtained with the hip position dictated by the type of surgery (discectomy = flexed; fusion = extended). For the purposes of this study, the first x-ray would be taken in the opposite position, the patient repositioned, and the procedure would continue with no additional radiographs. The third limb of the study will involve obtaining the same radiographs on unanesthetized volunteers with no history of low back pain within the preceding twelve months. This would permit the limitations of the first two limbs to be overcome, but would involve some x-ray exposure.

Number of subjects enrolled for reporting period:

Progress: Study is completed and has been accepted for presentation at the Scoliosis Research Society and the North American Spine Society Annual Meeting.

Date:	1 Sep 95	**Protocol**	94-80	**Status:**	Ongoing
Title:	The Use of Vitamin A in the Reversal of Corticosteroid Induced Defects in Wound Healing (Rattus Norvegius)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert Martindale, M.D.		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** COL Sidney Steinberg, MC K. Jeffery, MD, MCG MAJ Brad Waddell, MC MAJ David Craft, MS CPT Kim Vlach, MS, DVM SPC Demetrius Collins, Vet Technician			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Objective: To address the effectiveness of Vitamin A in reversing the detrimental effects of steroids on wound and tissue healing. The dose and duration at which Vitamin A accomplishes this will also be evaluated.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: This study is approximately sixty percent complete. There were 60 animals used during the last fiscal year.

Date:	1 Sep 95	**Protocol**	94-97	**Status:**	Ongoing
Title:	Basic General/Vascular Surgical Technique Training Laboratoary Using a Porcine Model				
Start Date:					
Principal Investigator(s): COL Manuel Ramirez, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** COL Sidney Steinberg, MC COL Richard Traugott, MC LTC David Rivera, MC LTC Robert Thomas, MC CPT Kim Vlach, MS, DVM SPC Demetrius Collins, Vet Technician		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Objective: Basic proficiency training of surgical interns, surgical residents, and other select surgical ancillary personnel approved by the principal instructor(s) in general soft tissue and vascular surgical techniques (both laparotomy and laparoscopic procedures). Advanced/refresher proficiency training of staff surgeons in new state-of-the-art or seldom used soft tissue and vascular surgical techniques.

Technical Approach: The training laboratory shall be conducted twice monthly (normally the 2nd & 4th Thursday of each month). Each laboratory session shall be scheduled for 1200 - 1500 hours on the appointed day. One pig shall be used for each laboratory session. At least one instructor shall be present and conduct each training session. Not more than 4 students will be trained during a given laboratory.

Number of subjects enrolled for reporting period:

Progress: This protocol was amended to include microvascular surgical training for staff and residents using the rat (Rattus norvegicus). It is anticipated that 24 rats per year (6 animals each quarter); surgical training sessions would average approximately one a month. The rat is an ideal surgical model for this type of training because the small size of its blood vessels closely approximates the vessels in the human hand. Lower phylogenetic species do not possess the same type of blood vessels as mammals and thus would not provide realistic training.

Date:	1 Sep 95	**Protocol**	95-13	**Status:**	Ongoing
Title:	Utilization of Goats (Capra hircus) For Advanced Trauma Life Support (ATLS) Trianing of DOD Medical Department Personnel				
Start Date:					
Principal Investigator(s): COL Manuel Ramirez, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** LTC Joseph Erpelding , MC LTC David Rivera, MC LTC Terrence Woods, MC MAJ John Hamelink , MC CPT Kim Vlach, MS, DVM SPC Demetrius Collins, Vet Technician		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Objective: Frequently, physicians are called upon to administer life-saving care to trauma patients. In many cases, these physicians are not familiar with these life-saving procedures, e.g., insertion of a chest tube, cricothyroidotomy, pericardiocentesis, diagnostic peritoneal lavage, or venous cutdown. The objective of this training is to teach physicians five safe, life-saving methods.

Technical Approach: The ATLS training couse offers the opportunity in the treatment of blunt and penetrating trauma in sufficient amount to train 48 physicians, dentists, nurses, physician assistants, and other health care professionals. This course is dedicated to the first hour of initial assessment and transport of trauma patients. For this reason, live animal models are used in the ATLS program as a teaching method for hands-on instruction in surgical techniques and trauma resuscitation.

Number of subjects enrolled for reporting period:

Progress: This protocol was amended to include microvascular surgical training for staff and residents using the rat (Rattus norvegicus). It is anticipated that 24 rats per year (6 animals each quarter); surgical training sessions would average approximately one a month. The rat is an ideal surgical model for this type of training because the small size of its blood vessels ciosely approximates the vessels in the human hand. Lower phylogenetic species do not possess the same type of blood vessels as mammals and thus would not provide realistic training.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-27	**Status:**	Ongoing

Title:	SWOG 8809 - A phase III study of alpha-interferon consolidation following chemotherapy with Promace-MOPP (Day 1-8) in patients with low grade malignant lymphomas
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology	**Associate Investigators:** Jayanti K. Sen, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Closed

Study Objective: To compare the disease-free survival of patients with low grade malignant lymphoma who receive alpha interferon consolidation therapy after intensive induction with chemotherapy-radiation therapy, to those who receive induction therapy alone. To determine the complete response rate, response duration and survival of low grade lymphoma patients treated with ProMACE-MCPP (day 1-8). To compare the toxicities of induction and induction plus consolidation therapy in this patient population.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: One (1)

Progress: One patient enrolled who has since relapsed. He has retired from the military and now being followed at Keesler AFB, Mississippi.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-29	**Status:**	Ongoing

Title:	SWOG 8854 (ECOG 1189, NCCTG 898051) Prognostic value of cytometry measurements of breast cancer DNA from postmenopausal patients with involved nodes and receptor positive tumors: A comparison protocol to SWOG 8814
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology	**Associate Investigators:** Karen Bowen, MAJ, MC Robert D. Ranlett, LTC, MC Arthur Wozniak, LTC, MS Stephen Oswald, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Closed

Study Objective: To determine if ploidy analysis of breast cancer by routine clinical flow cytometry (FCM) technique can predict response to therapy and survival of patients registered to SWOG 8814. To determine if ploidy analysis by image processing technique more accurately predicts patient response to therapy and survival than ploidy analysis by FCM.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled for reporting period: Two patients enrolled.

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-30	**Status:**	Ongoing

Title:	SWOG 8814 (ECOG-4188, NCCTG-883051) Phase III Comparison of adjuvant chemoendocrine therapy with CAF and concurrent or delayed tamoxifen to tamoxifen alone in postmenopausal patients with involved axillary nodes and positive receptors
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology	**Associate Investigators:** Robert D. Ranlett, LTC, MC Karen Bowen, MAJ, MC Kenneth Fink, LTC, MC Stephen Oswald, COL, MC Raj Gupta, MD
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Closed

Study Objective: To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen and/or progesterone receptors treated with standard adjuvant therapy with long-term tamoxifen, or with chemoendocrine therapy with CAF, followed by long-term tamoxifen, or with concurrent chemoendocrine therapy with tamoxifen and CAF. To compare the relative toxicity of the three therapies.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: Four patients enrolled

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-31	**Status:**	Ongoing

Title:	SWOG 8897 (EST-2188, CALGB-8897, INT0102) Phase III Comparison of adjuvant chemotherapy with or without endocrine therapy in high-risk, node negative breast cancer patients, and a natural history follow-up study in low-risk, node negative patients
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology	**Associate Investigators:** Karen Bowen, MAJ, MC Robert D. Ranlett, LTC, MS Arthur Wozniak, LTC, MS Stephen Oswald, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Closed

Study Objective: To compare disease-free survival (DFS) and overall survival (S) of high risk primary breast cancer patients with negative axillary lymph nodes treated with standard adjuvant chemotherapy with CMF for six cycles or with chemotherapy using CAF for six cycles. To assess the value of the addition of tamoxifen for five years compared to no tamoxifen in these patients. To compare the relative toxicity of the therapies. To assess the prognostic significance of DNA flow cytometry in patients with small, occult invasive breast cancer treated by local therapy only. To evaluate the DFS and S of low risk invasive breast cancer determined by receptor status, tumor size and S phase treated by local therapy only.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: Six patients enrolled.

Progress: One patient died due progression of disease, and one patient taken off study due to drug toxicity. There have been no other problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-34	**Status:**	Ongoing

Title:	SWOG 8931 (EST-3189, INT-0108) Phase III Comparison of Cyclophosphamide, Doxorubicin, and 5-Fluorouracil (CAF) and a 16-Week Multi-Drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node Positive Breast Cancer
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki,MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology	**Associate Investigators:** Karen Bowen, MAJ, MC Raj R.Gupta, M.D. Stephen Oswald, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Closed

Objective: To compare disease-free and overall survival in node positive receptor negative breast cancer patients receiving adjuvant CAF or a 16-week multi-drug chemotherapy regimen. To compare toxicities of adjuvant CAF and a 16-week multi-drug regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: Two patients enrolled

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-35	**Status:**	Ongoing
Title:	SWOG 8947 Central lymphoma serum repository protocol. (Companion study to SWOG 8516, 8736, 8809 or 8816)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Stephen Oswald, COL, MC Karen Bowen, MAJ, MC Kenneth Fink, LTC, MC Raj Gupta, MD			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To establish a central lymphoma serum repository that will serve as a resource to provide specimens for current and future scientific studies. To utilize the SWOG database to perform clinicopathologic correlations with the results of those studies.

Technical Approach: Blood sample will be drawn and shipped to the Serum Repository Laboratory for testing.

Number of subjects enrolled for reporting period: Two patients enrolled

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-41	**Status:**	Ongoing
Title:	SWOG 8736 Treatment of localized non-Hodgkin's lymphoma: Comparison of chemotherapy (CHOP) to chemotherapy plus radiation therapy				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Kenneth Fink, LTC, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: The primary study objective is to evaluate, in a cooperative group setting, the difference in survival, time to treatment failure and toxicity of two curative approaches to the treatment of patients with localized, intermediate or high grade, non-Hodgkin's lymphoma. The first treatment approach is chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) for eight cycles. The second uses CHOP for three cycles followed by involved field radiation therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: One patient enrolled.

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-50	**Status:**	Closed
Title:	SWOG 8851 Phase III comparison of combination chemotherapy (CAF) and chemohormonal therapy (CAF + Zoladex or CAF + Zoladex + Tamoxifen) in premenopausal women with axillary node-positive, receptor-positive breast cancer -- intergroup				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Robert D. Ranlett, LTC, MC Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Stephen Oswald, COL, MC Karen Bowen, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To compare the recurrence rates, disease-free intervals (DFI), and hormone-receptor-positive survival for premenopausal women with axillary lymph node-positive breast cancer given adjuvant therapy with chemotherapy (CAF) alone or chemotherapy (CAF) followed by Zoladex (Z) or chemotherapy (CAF) followed by Zoladex plus Tamoxifen (X + T). We will compare CAF with CAF + Z and CAF + Z with CAF + Z + T. To compare the relative toxicities of these 3 regimens. To assess the effect of CAF, CAF + Z, and CAF + Z + T on hormone levels (LH, FSH, and estradiol) in premenopausal women treated with these adjuvant therapies.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: No patients enrolled.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-53	**Status:**	Ogoing
Title:	SWOG 8952 Treatment of advanced Hodgkin's disease - A randomized Phase III study comparing ABVD vs MOPP/ABV hybrid				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Jayanti K. Sen, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed			

Study Objective: To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, disease-free survival, failure-free survival and both immediate and long-term toxicities. To compare the rate of drug delivery of the anti-neoplastic agents, especially the comparative dose rate of ABV in the two treatment groups. To examine the prognostic importance of time to response, performance status, age, presence of bulky disease, C-reactive protein, erythrocyte sedimentation rate, and prior radiotherapy on survival.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 2

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-55	**Status:**	Ongoing
Title:	SWOG 9013 A prospective randomized comparison of combined modality therapy for squamous carcinoma of the esophagus: Chemotherapy plus surgery alone for patients with local regional disease. Phase III intergroup				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Kenneth Fink, LTC, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To compare, using a prospective controlled randomized study design, the outcomes of therapy of surgery alone, versus pre- and post-operative chemotherapy and surgery for patients with local regional esophageal cancer. Outcome is defined as survival and relapse pattern. To assess the toxicities of a multimodality approach to esophageal carcinoma involving systemic chemotherapy and surgery. The toxicities of surgical resection, as initial therapy or following chemotherapy will be assessed as operative morbidity and mortality. To compare the local and distinct control rates with the two approaches and to define the pattern of failure. To compare the impact on overall and disease free survival of multimodality therapy with surgery alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: Two patients enrolled.

Progress: One patient developed respiratory complication and pneumonia and succumbed. The other patient is doing well.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-68	**Status:**	Closed
Title:	SWOG 9028 A Phase III Randomized trial of combination therapy for multiple myeloma. Comparison of 1) VAD to VAD/Verapamil/Quinine for induction with crossover to VAD/Verapamil/Quinine for VAD induction failures; 2) Alpha-2-b Interferon plus prednisone for remission maintenance				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Kenneth Fink, LTC, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To compare the effectiveness of the VAD chemotherapy regimen when administered alone or in combination with chemosensitizers (verapamil/quinine) intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma. The effectiveness of VAD plus verapamil and quinine for non-responders and progressors of the VAD induction regimen will also be investigated. This will be evaluated in terms of relapse-free and overall survival and P-glycoprotein expression prior to therapy and at the end of induction therapy in relation to the induction therapy arm. To compare the value of Intron-A (alpha-2b interferon) maintenance versus Intron-A plus prednisone for patients proven to achieve at least partial remission (50% tumor regression). The effectiveness of the two maintenance arms will be compared in terms of the duration of relapse-free survival and overall survival from the time of randomization to maintenance therapy. The time from relapse to death will also be assessed in relation to objectives 1 and 2. To evaluate the presence and prognostic significance of Ki-67 and P-glycoprotein in multiple myeloma via serial studies of bone marrow myeloma cells by immunophenotyping. These immunophenotypic markers will be assessed prior to therapy, after completion of induction chemotherapy and/or at the time of relapse and related to clinical findings of drug-sensitivity or resistance to the treatment administered. Moreover, the expression of P-glycoprotein will be related to relapse free and overall survival and to whether the patient receives chemosensitizers along with VAD chemotherapy to determine whether the sensitizers inhibited the development of P-glycoprotein expression. To evaluate the relationship between the magnitude of cytoreduction and survival. To evaluate the significance of pretreatment serum lactic dehydrogenase (LDH) as a marker for aggressive myeloma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: One patient enrolled.

Progress: Patient died due progression of disease.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	91-69	**Status:**	Ongoing
Title:	SWOG 9111 (EST-1690) Post-operative adjuvant interferon alpha-2 in resected high risk primary and regionally metastatic melanoma, intergroup				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Stephen Oswald, COL, MC Karen Bowen, MAJ, MC Kenneth Fink, LTC, MC Raj Gupta, MD			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To establish the efficacy of 1 year at maximally tolerable dosages (IV and SC) interferon alpha-2 as an adjuvant to increase the disease free interval and overall survival in patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence. To evaluate the efficacy and tolerance of long-term interferon alpha-2 at 3 MU/d (Sc TIW) as an adjuvant to increase the disease-free survival and overall survival of patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence with melanoma, in comparison to 1 year of treatment of maximally tolerable dosages.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: No patients enrolled.

Progress: NA

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	95-16	**Status:**	Ongoing
Title:	SWOG 9333 - A Randomized Controlled Trial of Mitoxantrone and Etoposide versus Daunomycin and Cytosine Arabinoside as Induction Chemotherapy in Patients Over Age 55 with Previously Untreated Acute Myeloid Leukemia, Phase III				
Start Date:	February 1995		**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Kenneth Fink, LTC, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: The goal of this study is to improve the complete response rate and disease-free survival in patients over age 55 by designing a remision induction regimen that will decreae toxicity and increase anti-leukemic effect compared with standard induction therapy of daunomycin and cytosine arabinoside.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: No patients enrolled.

Progress: NA.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-6	**Status:**	Ongoing
Title:	SWOG 9008 Trial of adjuvant chemoirradiation after gastric reaction for adenocarcinoma, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Paulino O. Vasallo, LTC, MC Kenneth Fink, LTC, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: 1) A comparison of overall and disease free survival between patients being treated with surgical resection only and those being treated with surgery plus adjuvant therapy. 2) A comparison of incidence and patterns of disease failure between surgery and surgery plus adjuvant therapy treated patients. 3) An assessment of patient tolerance of upper abdominal chemoradiation after gastric resection.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: No patients enrolled.

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-7	**Status:**	Closed
Title:	SWOG 9108 (CALGB-9011, NCIC-CTGCL.1) A Phase III comparison of fludarabine phosphate vs chlorambucil vs (fludarabine) phosphate plus chlorambucil in previously untreated B-cell chronic lymphocytic leukemia				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Kenneth Fink, LTC, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: 1) To compare in previously untreated CLL patients the response rates and progression free survival with the following three therapeutic regimens: i) fludarabine phosphate, ii) chlorambucil and iii) fludarabine phosphate + chlorambucil. 2) To determine whether the quality of life (need for transfusions, incidence of infections, and performance status) is superior using any of the three regimens. 3) To determine whether these two drugs (fludarabine phosphate and chlorambucil) are non-cross-resistant by a crossover design for patients failing to respond to the single agent to which they are initially randomized.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled during this reporting period: No patients enrolled.

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-37	**Status:**	Ongoing
Title:	SWOG 9007 Cytogenic studies in leukemia patients, ancillary				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Kenneth Fink, LTC, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment. To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients. To provide quality control for all Southwest Oncology Group cytogenetic data.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled during this reporting period: one patient enrolled.

Progress: There have been no problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-38	**Status:**	Closed
Title:	SWOG 9031 A Double-blind placebo controlled trial of daunomycin and cytosine arabinoside with or without rhG-CSF in elderly patients with acute myeloid leukemia, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Raj R. Gupta, M.D. Kenneth I. Fink, LTC, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To compare the complete response rates and durations of survival in patients aged 65 or older with acute myeloid leukemia (AML) when treated with standard doses of cytosine arabinoside (Ara-C) and daunorubicin (DNR), with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). To assess the frequency and severity of toxicities of the two treatment regimens. To compare the duration of neutropenia and thrombocytopenia; the total number of febrile days; the number of days of antibiotic therapy; the number and type of infection episodes; and the number of hospital days in patients treated with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). To correlate biological parameters including cell surface immunophenotype, ploidy and cytogenetics with clinical response.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled to date: No patients enrolled in this study.

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-39	**Status:**	Ongoing
Title:	SWOG 9139 Adjuvant therapy of primary osteogenic sarcoma, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Kenneth Fink, LTC, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To estimate the time to treatment failure and survival rate of the three drug combination adriamycin, cisplatin, and ifosfamide as adjunctive treatment of osteosarcoma of the extremity. To evaluate histopathologic tumor necrosis following preoperative adriamycin, cisplatin, and ifosfamide. To assess the feasibility of determining histopathologic tumor necrosis in a cooperative e group setting. To assess the influence of clinical prognostic variables on disease outcome. To assess the toxicity of this regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: There are no patients enrolled in this study.

Progress: NA

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-49	**Status:**	Ongoing
Title:	SWOG 9019 A Phase III, Randomized prospective comparison between chemotherapy plus radiotherapy and the same chemotherapy plus radiotherapy together with surgery for selected Stage IIIA (positive mediastinal nodes) and selected Stage IIIB (no malignant effusion) non-small cell lung cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Kenneth Fink, LTC, MC Karen Bowen, MAJ, MC Clifford Threldkeld, LTC, MS Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, overall, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa (Ne-positive) and selected IIIb non-small cell lung cancer. To evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled during this reporting period: One (1):

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-50	**Status:**	Ongoing
Title:	SWOG 9035 Randomized trial of adjuvant immunotherapy with an allogenic melanoma vaccine for patients with intermediate thickness node negative malignant melanoma (T 3NOMO)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Kenneth Fink, LTC, MC, Paulino D. Vasallo, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To compare disease-free survival and overall survival between patients with T3NOMO malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patients with T3NOMO malignant melanoma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled during this reporting period: Two patients enrolled i n this study.

Progress: Both patients taken off-study. One patient changed his mind about doing the study and the other patient had a second malignancy to occur.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-94	**Status:**	Ongoing
Title:	SWOG 9336 - A Phase III Comparison Between Concurrent Chemotherapy Plus Radiotherapy, and Concurrent Chemotherapy Plus Radiotherapy Followed by Surgical Resection of Stage IIIA (N2) Non-Small Cell Lung Cancer				
Start Date: Dec 94			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Karen Bowen, MAJ, MC Kenneth Fink, LTC, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To evaluate the likelihood of response of hormone refractory, metastatic carcinoma of the prostate treated with F-FU and Roferon-A in order to assess whether this regimen should be advanced to further studies. To assess the qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled during this reporting period: No patients enrolled in this study.

Progress: NA

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-69	**Status:**	Ongoing
Title:	SWOG 9059 - Phase III Comparison of Standard Radiotherapy *versus* Radiotherapy Plus Simultaneous Cisplatin, *versus* Split-Course Radiotherapy Plus Simultaneous Cisplatin and 5-Fluorouracil, in Patients with Unresectable Squamous Cell Carcinoma of the Head and Neck				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Kenneth Fink, LTC, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To compare the effectiveness of standard radiation therapy alone to radiation therapy and simultaneous chemotherapy with cisplatin to split-course radiation therapy with cisplatin and 5-fluorouracil infusion in patients with unresectable Stage III and IV squamous cell carcinoma of the head and neck. Endpoints will include complete response rate, time to treatment failure, and overall survival. To compare the relative toxicities of these three treatment arms in this patient population. To compare patterns of relapse or treatment failure among these regimens. To further assess the role, timing, and success of surgery in patients achieving a response to non-operative therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: No patients enrolled in this study.

Progress: NA

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-70	**Status:**	Ongoing
Title:	SWOG 9129, Phase III Randomized Study of All-Trans Retinoic Acid *versus* Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients with Previously Untreated Acute Promyelocytic Leukemia				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Kenneth Fink, LTC, MC Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To compare the complete remission rate and disease-free survival of TRA to that achieved with conventional induction chemotherapy including Cytosine Arabinoside plus Daunorubicin in Patients with previously untreated APL. To compare the toxicities of TRA to those of Cytosine Arabinoside plus Daunorubicin as induction therapy in APL. To determine the value of maintenance therapy with TRA.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: No patients enrolled.

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	92-71	**Status:**	Closed
Title:	SWOG 9150 - Evaluation of Topotecan in Gastric Cancer, Phase II				

Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology	**Associate Investigators:** Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Kenneth Fink, LTC, MC Raj Gupta, MD
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Closed

Study Objective: To evaluate the response rate of gastric carcinoma treated with topotecan. To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled during this reporting period: None.

Progress:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	95-6	**Status:**	Ongoing
Title:	SWOG 9445 - Prognostic Factor Panel to Predict Preferred Therapy for Node Positive Postmenopausal Breast Cancer Patients (CAF vs Tamoxifen) (A Companion Protocol to SWOG 8814)				
Start Date:	Feb 95		**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Karen Bowen, MAJ, MC Stephen Oswald, COL, MC Kenneth Fink, LTC, MC Raj Gupta, MD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective:

Technical Approach: The objective of this study is to correlate a panel of markers with clinical outcome and responsiveness to adjuvant therapy of node positive post menopausal breast cancer patients who participated in SWOG 8814, and to confirm the results of the CALGB study, CALGB 8541, which suggested that c-erbB-2 expression is a strong predictor of the efficacy of CAF based adjuvant chemotherapy.

Number of subjects enrolled for this reporting period: No patients enrolled in this study.

Progress: NA

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-8	**Status:**	Ongoing
Title:	SWOG 9133 - Randomized Trial of Subtotal Nodal Irradiation versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III				
Start Date:				**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC				**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology				**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Clifford Threldkeld, LTC, MS Stephen Oswald, COL, MC Karen Bowen, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:				**Periodic Review Results:** Sep 95, Continue	

Study Objective: To compare the ability of two treatment regimens (radiation therapy alone or radiation plus chemotherapy), one of which will be chosen to treat the cancer. This study will also determine whether these treatments have any effect on the patients disease free survival, and whether the effects of treatment are different for different people based on age, gender, type of disease and number of disease sites.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-9	**Status:**	Closed
Title:	SWOG 9148 - A Phase II Study of Cisplatin Preceded by a 12-Hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (ARA-C) for Patients with Untreated Extensive Stage Small Cell and Non-Small Cell Lung Carcinoma				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Karen Bowen, MAJ, MC Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Clifford Threldkeld, LTC, MS Stephen Oswald, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To determine if the chemotherapy agents cisplatin, cytosine arabinoside (ARA-C) and Hydroxyurea when used together may be more effective in lung cancer patients than when used alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol:**	95-27	**Status:**	Ongoing
Title:	SWOG 9501 - A Phase II Trial of Fludarabine and Mitoxantrone (FN) for Treatment of Non-Hodgkins Lymphomas				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Hematology-Oncology		**Associate Investigators:** Stephen G. Oswald, COL, DO Kenneth I. Fink, LTC, MC Karen J. Bowen, MAJ, MC Raj R. Gupta, M.D.			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To estimate the two-year progression-free survival rate in patients with previously untreated low-grade non-Hodgkin's lymphoma treated with fludarabine and mitoxantrone, and to evaluate the toxicity of fludarabine and mitoxantrone in this group of patients.

Technical Approach: Patients who participate will receive fludarabine and mitoxantrone through a vein over a period of thirty minutes on the first day of treatment. Trimethoprim sulfa will be given by mouth daily throughout the treatment to help prevent infections. This treatment will be repeated every twenty-eight cycles as long as the disease is getting better.

Number of subjects enrolled this reporting period:

Progress:

Problems encountered:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-19	**Status:**	Ongoing
Title:	SWOG 9003 - Fludarabine for Waldenstrom's Macroglobulinemia (WM): A Phase II Pilot Study for Untreated and Previously Treated Patients				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen Bowen, MAJ, MC Stephen Oswald, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: The objective of this study is to find out how well patients respond and how well patients respond and how long their response lasts when treated with Fludarabine. Fludarabine is now being evaluated to determine its benefits and effectiveness on Waldenstrom's Macroglobulinemia. We want to learn more about this disease and how long it can be observed without chemotherapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-21	**Status:**	Ongoing
Title:	SWOG 9201 - Phase III, Trial to Preserve the Larynx: Induction Chemotherapy and Radiation Therapy versus Radiation Therapy				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** Kenneth I. Fink, LTC, MC RAJ R.Gupta, M.D. Karen Bowen, MAJ, MC Stephen Oswald, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To preserve the larynx by using non-surgical treatments. Three treatments will be compared: (1) chemotherapy followed by radiation, or (2) chemotherapy given at the same time, or (3) radiation alone.

Technical approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-22	**Status:**	Ongoing
Title:	SWOG 9205 - Central Prostate Cancer Serum Repository Protocol				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R.Gupta, M.D. Karen Bowen, MAJ, MC Stephen Oswald, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To serve as a repository for serum of patients with prostate cancer entered onto Southwest Oncology Group approved studies. The purpose of this activity is to provide the opportunity for study of new or existing markers or other tests in a prospective or retrospective fashion in order to test their usefulness as diagnostic or management tools in prostate cancer at all stages.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-28	**Status:**	Ongoing
Title:	SWOG 9158 - Evaluation of Trans Retinoic Acid and Alpha Interferon in Patients with Squamous Cell Carcinoma of the Lung (Stage IV)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R.Gupta, M.D. Karen Bowen, MAJ, MC Stephen Oswald, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective:To assess the response rate to trans-Retinoic Acid and Alpha Interferon used in a daily schedule for patients with advanced, well differentiated squamous cell carcinoma of the lung. To further define the qualitative and quantitative toxicities of this regimen administered to this patient population in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-29	**Status:**	Ongoing
Title:	SWOG 9216 - A Randomized Phase III Study of CODE Plus Thoracic Irradiation *versus* Alternating CAV and EP for Extensive Stage Small Cell Lung Cancer				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** Kenneth I.Fink, LTC, MC Raj R. Gupta, M.D. Karen Bowen, MAJ, MC Stephen Oswald, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To determine whether the CODE regimen plus thoracic irradiation is superior to standard alternating CAV and EP in the treatment of extensive stage small cell lung cancer in terms of: overall survival, time to disease progression, response rate, response duration, and quality of life.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-43	**Status:**	Ongoing

Title:	SWOG 9126 - A Controlled Trial of Cyclosporine as a Chemotherapy-Resistance Modifier in High Risk Acute Myeloid Leukemia, Phase III
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology	**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R.Gupta, M.D. Stephen G. Oswald, COL, MC Karen Bowen, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To compare the complete remission rate and duration of survival in patients with high-risk acute myeloid leukemia (AML), when treated with either chemotherapy (ara-C/Daunomycin) alone, or chemotherapy plus the resistance modifier cyclosporine-A (CyA): To estimate the frequency of p-glycoprotein expression and the correlation with prognosis in patients with relapsed AML, primary refractory AML, and secondary AML; to compare the frequency and severity of toxicity of the two treatment regimens; and to investigate the relationship between response to treatment and the blood levels of cyclosporine-A and daunorubicin achieved.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-44	**Status:**	Closed
Title:	SWOG 9237 - Evaluation of Topotecan in Refractory and Relapsing Multiple Myeloma, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen J. Bowen, MAJ, MC Stephen G. Oswald, COL, MC Clifford Threldkeld, LTC, MS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: To evaluate the response rate for refractory myeloma treated with topotecan; the qualitative and quantitative toxicities of topotecan administered in a Phase II study; and measure topoisomerase levels in multiple myeloma cells.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	9 Mar 95	**Protocol**	93-56	**Status:**	Ongoing
Title:	SWOG 9248 - A Phase II Trial of Paclitaxel (Taxol) in Patients with Metastatic Refractory Carcinoma of the Breast				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ,MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Hematology-Oncology		**Associate Investigators:** Kenneth I. Fink, LTC, MC Stephen Oswald, COL, MC Karen Bowen, MAJ, MC Raj R. Gupta, M.D. Clifford Threldkeld, LTC, MS			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective: To evaluate the subjective improvement in patients with symptomatic refractory carcinoma of the female breast treated with paclitaxel. Information obtained from patients in studies like this one can, in the future, help a doctor and a patient make treatment decisions.

Technical Approach: As outlined in SWOG protocol.

Number of Subjects Enrolled to Date: 0

Progress: One patient on study.

Problems Encountered: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-46	**Status:**	Closed
Title:	SWOG 9246 - A Phase II Evaluation of Taxol in Patients with Relapsed Non-Hodgkin's Lymphoma or Relapsed Hodgkin's Disease				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D Stephen G. Oswald, COL, MC Karen Bowen, MAJ, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Closed			

Study Objective: To assess the response rate of relapsed low grade non-Hodgkin's lymphoma, relapsed intermediate or high grade non-Hodgkin's lymphoma and relapsed Hodgkin's disease treated with taxol and to assess the qualitative and quantitative toxicities of taxol administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-53	**Status:**	Ongoing
Title:	SWOG 9221 - Phase III Double-Blind Randomized Trial of 13-Cis Retinoic Acid (13-cRA) to Prevent Second Primary Tumors (SPTs) in Stage I Non-Small Cell Lung Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Stephen G. Oswald, COL, MC Karen Bowen, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To compare daily oral administration of 13-Cis Retinoic Acid against placebo in preventing new primary lung tumors from patients having had surgical treatment of a Stage I non-small cell lung tumor.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled during this reporting period: 3

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	9 Mar 95	**Protocol:**	95-16	**Status:**	Ongoing

Title:	SWOG 9333 - A Randomized Controlled Trial of Mitoxantrone and Etoposide versus Daunomycin and Cytosine Arabinoside as Induction Chemotherapy in Patients Over Age 55 withPreviously Untreated.

Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Hematology-Oncology	**Associate Investigators:** Stephen Oswald, COL, MC Karen Bowen, MAJ, MC Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Clifford Threldkeld, LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To improve the complete response rate and disease-free survival in patients over age 55 by designing a remission induction regimen that will decrease toxicity and increase anti-leukemic effect compared with standard induction therapy of daunomycin and cytosine arabinoside.

Technical Approach: To assess the frequency and severity of toxicities and the durations of neutropenia, thrombocytopenia, and first hospitalization associatiated with the two induction chemotherapy regimens.

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	93-55	**Status:**	Ongoing

Title:	SWOG 9210 - A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD-P to VAD-P/Quinine for Induction; (2) Randomization of Prednisone Dose Intensity for Remission Maintenance

Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology	**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Stephen G. Oswald, LTC, MC Clifford Threldkeld, LTC, MS Karen Bowen, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To compare the effectiveness of the VAD-P chemotherapy regimen when administered alone or in combination with the chemosensitizer quinine. It will evaluate the chemosensitizing potential of quinine to reverse drug resistance.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled duirng this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-16	**Status:**	Ongoing

Title:	SWOG 9303: Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil versus 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology	**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen J.Bowen, MAJ, MC Stephen G. Oswald, COL, MC Clifford Threldkeld, LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To determine whether 5FU, levamisole and radiation therapy results in superior overall survival when compared to 5FU and levamisole without radiation therapy in the management of patients with completely resected pathologic stage (T4bNo-2) colon cancer and selected patients with (T3N1-2) colon cancer. Disease free survival, patterns of failure and toxicity will also be evaluated.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-17	**Status:**	Ongoing

Title:	SWOG 9306: Conservative Treatment of Adenocarcinoma of the Distal Rectum: Local Resection Plus Adjuvant 5FU/Radiation Therapy, A Phase II Intergroup Study
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology	**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen J. Bowen, MAJ, MC Stephen Oswald, COL, MC Clifford Threldkeld, LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To determine whether the survival of patients with T1 and T2 adenocarcinoma of the rectum who have been treated with limited, sphincter sparing surgery is comparable to that of historical controls treated with radical surgery (abdominoperineal resection). This study will determine the efficacy and toxicity of a combined modality approach using conservative surgery with post-operative radiation therapy and 5-FU.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-21	**Status:**	Ongoing
Title:	SWOG 9005: Double Blind Randomized Trial of the Anti-Progestational Agent Mifepristone in the Treatment of Unresectable Meningioma, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen J.Bowen,MAJ, MC Stephen Oswald, COL., MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To find out whether patients will respond and how long their response lasts if treated with the experimental antiprogestational agent mifepristone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 1 (transfer from BAMC)

Progress: No problems encountered during this reporting period.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-22	**Status:**	Ongoing

Title:	SWOG 9250: Phase III Intergroup Prospectively Randomized Trial of Perioperative 5-FU after Curative Resection Followed by 5-FU/evamisole for Patients with Colon Cancer
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology	**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen J.Bowen, MAJ, MC Stephen Oswald, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To determine if adjuvant therapy with one week of continuous 5-FU given within 24 hours of a curative colon resection followed by 12 months of 5-FU/levamisole is effective in prolonging the disease free interval and increasing survival in patients with Dukes B3 or C colon cancer, when compared to patients who are treated with 5-FU/levamisole only.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 2

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-23	**Status:**	Ongoing
Title:	SWOG 9312: Phase II Evaluation of Cisplatin + 5FU + Radiation Therapy in Patients with Locally Advanced/Inoperable Bladder Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen J. Bowen, MAJ, MC Stephen Oswald, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To assess the response rate and the feasibility of utilizing cisplatin + 5FU + radiation therapy in patients with locally advanced/inoperable carcinoma of the bladder. This study will also assess the qualitative and quantitative toxicities of this combination.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-24	**Status:**	Ongoing

Title:	SWOG 9300: A Randomized Phase II Evaluation of All Trans Retinoic Acid (ATRA) with Interferon-Alfa 2a (IFNOalfa 2a) or All Trans Retinoic Acid with Hydroxyurea (H) in Patients with Newly Diagnosed Chronic Myelogenous Leukemia in Chronic Phase
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology/Pathology	**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen Bowen, MAJ, MC Stephen Oswald, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To find out how well patients respond and how long their response lasts when treated with either All Trans Retinoic Acid and hydroxyurea or All Trans Retinoic Acid and interferon. This study will also find out what kind of side effects these drugs cause and how often they occur; and examine the cells of the patient's bone marrow to find out if there is any connection between response to treatment and the type of cells that are identified in the bone marrow.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 1

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-38	**Status:**	Ongoing
Title:	SWOG 9332: Phase II Trial of Adriamycin versus Taxol versus Taxol plus Adriamycin Plus G-CSF in Metastatic Breast Cancer				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R. Gupta, M.D. Karen J.Bowen, MAJ, MC Stephen Oswald, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To compare the activity of Taxol as a single agent with that of single-agent Adriamycin and with Adriamycin and Taxol in combination in patients with metastatic breast cancer, in an effort to determine the relative efficacy and toxicity of the three regimens in patients with previously untreated metastatic breast cancer. This study aims to (1) slow or stop the growth of the tumor, (2) gain information about the disease, (3) help identify better treatments for cancer of the breast, (4) help define the side effects and effectiveness of Taxol when it is used in combination with a commonly used chemotherapeutic agent for breast cancer, Adriamycin, and (5) assess changes in quality of life that occur while the patient is receiving treatment.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 1

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-45	**Status:**	Closed
Title:	SWOG 9308: Randomized Trial Comparing Cisplatin Plus Intravenous Navelbine in the Treatment of Previously Untreated, Stage IV Non-Small Cell Lung Cancer Patients				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** Kenneth I. Fink, LTC, MC Raj R.Gupta, M.D. Karen Bowen, MAJ, MC Stephen Oswald, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Closed		

Study Objective: The objectives of this Phase II study are to (1) compare the effect of cisplatin alone with that of intravenous Navelbine plus cisplatin on tumor response rate, survival, and time to treatment failure in patients with Stage IV non-small cell lung carcinoma, and (2) compare the toxicity of the two treatment regimens in patients with Stage IV non-small cell lung carcinoma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 1.

Progress: One patient registered on protocol, but was taken off study due to spinal cord compression (not protocol related).

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-73	**Status:**	Ongoing
Title:	SWOG 9307: Extended Administration of Oral Etoposide and Oral Cyclophosphamide for the Treatment of Poor Prognosis Extensive Disease Small Cell Lung Cancer, Phase II Pilot				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology/Pathology			**Associate Investigators:** Kenneth I.Fink, LTC, MC Stephen Oswald, COL, MC Karen J.Bowen, MAJ, MC Raj R. Gupta, M.D.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To estimate the response rate of extended oral administration of etoposide and cyclophosphamide in poor prognosis extensive disease small cell lung cancer; to evaluate the qualitative and quantitative toxicities of this regimen administered in a Phase II study; and to investigate possible correlations between peak and trough plasma etoposide levels versus complete response, toxicity, and survival.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol**	94-89	**Status:**	Ongoing
Title:	SWOG 9208 - Health Status and Quality of Life (OOL) in Patients with Early Stage Hodgkins Disease: A companion Study to SWOG 9133, Ancillary				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Kenneth I.Fink, LTC, MC Stephen Oswald, COL, MC Karen J.Bowen, MAJ, MC Raj R. Gupta, M.D.			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Study Objective:

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 93-54	**Status:** Ongoing	
Title: SWOG 9157 - Trial of All Trans-Retinoic Acid in Hepatoma, Phase II			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Kenneth I.Fink, LTC, MC Stephen Oswald, COL, MC Karen J.Bowen, MAJ, MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To compare thrice dialy oral administration of all trans-retinoic acid or placebo on three week cycles for hepatoma, a malignancy for which no good tretment exists. Evidence of efficacy will lead to a wider clinical study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	**Protocol** 93-20	**Status:** Ongoing
Title:	SWOG 9015 - A Randomized Trial of Pre- and Post- Operative Chemotherapy Compared to Surgery Alone for Patients with Operable Non-Small Cell Carcinoma of the Lung, Phase III		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Kenneth I.Fink, LTC, MC Stephen Oswald, COL, MC Karen J.Bowen, MAJ, MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To compare how well patients respond and how long the response lasts when treated with a combination of VP-16 and carboplatin before and after surgery or surgery alone, and to estimate the side effects of these drugs and how often they occur.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 93-7		**Status:** Ongoing
Title: SWOG 9104 - Evaluation of Doxorubicin/Vinblstine Combined with Inhibitors (Trifluoperazine/Verapamil) of P-Glycoprotein in Patients with Advanced Renal Cell Carcinoma, Phasell			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Kenneth I.Fink, LTC, MC Stephen Oswald, COL, MC Karen J.Bowen, MAJ, MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective:

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 92-40		**Status:** Ongoing
Title: SWOG 9151 Evaluation of Topotecan in Hepatoma			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Kenneth I.Fink, LTC, MC Stephen Oswald, COL, MC Karen J.Bowen, MAJ, MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: To evaluate the response rate of topotecan. To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	1 Sep 95	Protocol 92-48	**Status:** Ongoing
Title:	SWOG 9054 Ancillary Bone Mineral Density Study in Premenopausal Women on EST 5188		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Kenneth I.Fink, LTC, MC Stephen Oswald, COL, MC Karen J.Bowen, MAJ, MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective:

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date: 1 Sep 95	**Protocol** 93-45	**Status:** Ongoing	
Title: SWOG 9240 - A Phase II Trial of CVAD for Treatment of Non-Hodgkins Lymphoma			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology/Pathology		**Associate Investigators:** Kenneth I.Fink, LTC, MC Stephen Oswald, COL, MC Karen J.Bowen, MAJ, MC Raj R. Gupta, M.D.	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue	

Study Objective: This study will evaluate the effectiveness of the CVAD chemotherapy regimen in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for this reporting period: 0

Progress: No patients registered.

DETAIL SUMMARY SHEET

Date:	12 Jan 95	**Protocol**	95-4	**Status:**	Ongoing
Title:	A Randomized, Double-Blind, Placebo Controlled, Parallel Group Study to Examine Safety, Efficacy and Pharmacokinetics of a 3-Day Loading + Maintenance Infusion Regimen of 619C89 Mesylate Injection in the Treatment of Patients with Symptoms of Acute Stroke.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Leonard J. Leone, MAJ, MC			**Facility:** USA MEDDAC, FT Benning, GA		
Department/Service:			**Associate Investigators:** Roger Strickland, LTC, MC Bruce Chamberlain, MAJ, MC William Yost, MAJ, MC Stephen Raborn, MAJ, MC Marini Domenic, CPT, MC Paul Lester, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: The purpose of this study is to examine the safety of teh maximum tolerated loading infusion and maintenance dose infusion for 72 hours of 619C89 using reported adverse experiences, vital signs and laboratory parameters.

Technical Approach: This study will have a placebo controlled, double-blind, parallel group design. Eligible patients presenting to the hospital within 12 hours of suspected stroke will be randomized to receive either 619C89 or matching placebo for 3 days.

Progress: Study has been suspended pending further notification from the FDA at which time the protocol will be reviewed by the IRC.

Number of Subjects Enrolled:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Feb 95	**Protocol:**	94-86	**Status:**	Ongoing

Title:	Tobacco Use Cessation Intervention of Military Personnel and Families
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Frances K.L. Bushnell, CPT, AN	**Facility:** Blanchfield Army Hospital FT Campbell, KY
Department/Service: Preventive Medicine	**Associate Investigators:** Elaine McIntosh, RN Barbara Forbes, RN Eric Edwards, MAJ, RN Jacqueline Goffaux, MS, Ph.D. Kimberly Matthews, LT, RN Craig Heim, M.D.
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95,Continue

Study Objective: To evaluate the relative effectiveness of two tobacco use cessation interventions (American Cancer Society Fresh Start and Vanderbilt University Medical Center Structured Behavior Counseling and Physiological Monitoring Program) in reducing tobacco use among military personnel and dependents; and to evaluate the relative contribtion of planned increases in phsysical activity when added to both of these tobacco cessation programs.

Technical Approach: The study will utilize a randomized clinical trial design. Randomization will occur with the flip of a coin with each subject entered into the study. Heads will go into the experimental group and tails will go to the control group.

Number of Subjects Enrolled to Date: Three hundred and fourteen.

Progress: Screening and intervention have been completed for 314 participants. Analysis has been completed on intake questionnaire for demographics and predictors as well as for 9 month followup.

Problems Encountered:

SUMMARY DETAIL SHEET

Date:	1 Sep 95	**Protocol**	93-33	**Status:**	Ongoing
Title:	Vocal Cord Function and Voice Quality Evaluation of Active Duty U.S. Army Drill Instructors				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Pearline McKenzie, CPT, MC		**Facility:** USA MEDDAC, Ft Jackson, SC			
Department/Service:		**Associate Investigators:**			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Continue			

Objective: To document the laryngeal pathology and record the acoustic effects of acute voice abuse in active duty US Army drill instructors during periods of intense training.

Technical Approach: Subjects will be chosen for videostroboscopy and acoustic analysis preceding and during the early phases of small unit training.

Number of subjects enrolled for the reporting period:

Progress: The principal investigator for this study has changed to CPT Pearline McKenzie at WRAMC, Head and Neck Surgery Service.

DETAIL SUMMARY SHEET

Date:	9 Feb 95	**Protocol**	95-10	**Status:**	Ongoing
Title:	Influence of Parenteral Progesterone Administration on the Prevalence and Severity of Mastodynia in Active Duty Servicewomen: A Multi-institutional Cross-Sectional Study.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Herman M. Bartell, MAJ, MC Susan Dunlow, CPT, MC			**Facility:** Blanchfield Army Hospital FT Campbell, KY		
Department/Service: Psychiatry/Neurology			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To provide a better understanding on the causes of mastodynia.

Technical Approach: This study proposes to poll a large number of servicewomen. A questionnaire will be used to document the presence and measure the severity of breast pain. A cross-sectional method will be used to compare the frequency of mastodynia between women receiving long-term progesterone supplementation (for contraception) and those not receiving supplementation.

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Feb 95	**Protocol**	95-11	**Status:**	Ongoing
Title:	Influence of Parenteral Progesterone Administration on the Prevalence and Severity of Mastodynia in Active Duty Servicewomen: A Multi-institutional Cross-Sectional Study.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Susan Gaire, CPT, MC			**Facility:** Martin Army Hospital FT Benning, GA		
Department/Service: OB/GYN			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To provide a better understanding on the causes of mastodynia.

Technical Approach: This study proposes to poll a large number of servicewomen. A questionnaire will be used to document the presence and measure the severity of breast pain. A cross-sectional method will be used to compare the frequency of mastodynia between women receiving long-term progesterone supplementation (for contraception) and those not receiving supplementation.

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Feb 95	**Protocol**	94-18	**Status:**	Completed
Title:	Treatment of Adult Patients with Chickenpox with Short Course Oral Acyclovir				

Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Steve Reissman, DO	**Facility:** Martin Army Hospital FT Benning, GA
Department/Service: Family Practice	**Associate Investigators:** Ted D. Epperly, LTC,MC John P. Fogartay, COL, MD
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Completed

Study Objective: The purpose of this study is to determine if oral acyclovir, when used for 5 days is effective in the treatment of adults who have chickenpox.

Technical Approach: As soon as a patient develops chickenpox, that patient will be sent to the hospital so as not to infect other soldiers and to rest. Each patient will have a 50/50 chance of getting the drug acyclovir or placebo in addition to Tylenol and an anti-itch medication.

Number of Subjects Enrolled to Date: 15

Progress: Low volume of chicken pox patients this year.

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Feb 95	**Protocol**	94-56	**Status:**	Completed
Title:	Musculoskeletal Overuse Injury: Bone Mass and Fitness				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Todd Dombroski, MAJ, MC			**Facility:** Martin Army Hospital FT Benning, GA		
Department/Service: Sports Medicine			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Completed		

Study Objective: To determine the bone mineral density of the lumbar spine, calcaneus, proximal and distal tibia, and hip on a subset of military recruits at the beginning and end of basic training.

Technical Approach: A population of 200 military recruits in the inprocessing period and first week of basic training and who exhibit no signs or symptoms of stress fracture, tendinitis, bursitis, plantarfascitis, or patellofemoral pain will be scannead on the Hologic 2000. They will be rescanned at the end of the twelve week army training program.

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	13 Apr 95	**Protocol**	95-20	**Status**	Ongoing

Title:	Impact of Telemedicine/Telenursing on Patients & Costs
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Loretta Schlachta, LTC, AN	**Facility:** USA MEDDAC, FT Stewart, GA
Department/Service: Nursing	**Associate Investigators:** Lisa Bush, RN, MSN Richard McKnight, MAJ, MC Thomas E. Knuth, MAJ, MC Betsey S. Blakeslee, PH.D Placidia Clark, 1LT, AN Noel Poindexter, 1LT, AN Jack Horner, DAC Thomas Baker, 2LT Arlene Lowenstein, Ph.D Maribeth Johnson, Consultant
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To identify the impact of home based telenursing on patients' health outcomes and hospital utilization costs.

Technical Approach: The study is designed to answer the question "Will telenursing effect healthcare utiliation?" To answer the question, the latest low band width telemedicine technology in the form of desktop computers with a motion camera and appropriate medical instrumentation will be placed in sample patients' homes, and patients will be "visited" electronically by a telenurse.

Progress: Project not started, awaiting funding.

Number of Subjects Enrolled to Date:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Mar 95	**Protocol**	95-17	**Status:**	Ongoing
Title:	Study of Chlamydia Trachomatis in Military Women: Prevalence, Risk Factors, and a Cost Benefit analysis of Early Diagnosis and Treatment.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Rose Marie Hendrix, LTC,MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Preventive Medicine			**Associate Investigators:** Charlotte Gaydos, M.D. Kelly McKee, COL, MC Thomas C. Quinn, M.D. Anne M. Rompalo, M.D.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To determine the prevalance of Chlamydia Trachomatis by anonymously testing urine by LCR and to determine risk factors for infection by the administration of an anonymous questionnaire to 2,000 female basic training recruits at FT Jackson, SC to establish prevalence.

Technical Approach: A large number of active duty female soldiers who are symptomatic and presenting for treatment will be given the questionnaire and offered urine testing.

Number of Subjects Enrolled to Date:

Progress: Due to a long delay in receiving funds, it was necessary to make changes to the original anonymous screening plan. Since the LCR test is about to become FDA approved, the proposed anonymous screening of 2,000 incoming recruits, now be not anonymous, because of ethical considerations. Licensure is expected by the end of the year. A pilot study is planned for January.

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	1 Jul 94	**Protocol**	94-19	**Status:**	Ongoing
Title:	Carbohydrate Deficient Transferrin as a Measure of Alcohol Use Among US Army Personnel.				

Start Date:	**Est. Compl. Date:**
Principal Investigator(s): COL Gerald Cross, MC	**Facility:** USA MEDDAC, FT Stewart, GA
Department/Service: Family Practice	**Associate Investigators:** MAJ Kim J. Zagorski, MC CPT Kelly A. Murray, MC John P. Allen, PhD Sidney Levine, PhD MAJ Marsha L. Bloodworth, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:** Sep 95, Continue

Study Objective: To determine if a substance in blood call "carbohydrate deficient treansferrin" can accccurately measure past use of alcohol and how results of this test relate to other laboratory and interview measures of drinking. Subjects are asked to submit a small blood sample which is analyzed by a laboratory. They will complete questionnaires and interviews on their use of alcohol and problems that drinking may be causing them. All procedures with the subject are expected to be completed in a single visit.

Technical Approach: Three hundred subjects will be enrolled in the study. The sample will be stratified on this basis of self-reported time since last drink. One hundred twenty-five subjects will have consumed alcohol within the seven days before assessment; one hundred twenty-five between eight and fourteen days prior to assessment; and fifty between fifteen and twenty-one days before assessment. Subjects will selected sequentially from inidviduals receiving the ADAPCP evaluation and in proportion to the required three subsample sizes. Two research assistants, trained by staff from the University of Connecticut in the Coordinating Cener for Project MATCH, will conduct all assessments.

Number of Subjects Enrolled to Date: Twenty-three.

Progress: Slow enrollment of eligible participants due to the fact that they feel that anything found in their blood might be used against them and affect their careers. The study is reapproved for six months pending reevaluation by Principal Investigator, at which time the IRC will review.

Problems Encountered: See above.

DETAIL SUMMARY SHEET

Date:	1 Jul 94	**Protocol**	93-58	**Status:**	Completed
Title:	Periodic Prenatal Nursing Interaction for Primigravidas: Does it Affect Preterm Birth Rate and Prenatal Care Compliance?				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kathleen M. Ford, CPT, RN, BSN			**Facility:** USA MEDDAC, FT Stewart, GA		
Department/Service: Nursing			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Completed		

Study Objective: This study will examine empirically the relationship between regular telephonic nursing interaction with primigravidas during the antaepartal period and the rate of preterm births . It will use questionnaires and existing medical records.

Technical Approach:

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	Dec 93	**Protocol**	94-26	**Status:**	Completed
Title:	A Proposed Study of the Validity of the PK and PS Scales of the MMPI-2: PTSD and Incest				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Diane M. Zierhoffer, CPT, MSC			**Facility:** USA MEDDAC, FT Stewart, GA		
Department/Service: Psychiatry			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Completed		

Study Objective: The purpose of this proposed study will be to investigate to what extent the Post Traumatic Stress Disorder - Keane (PK) and Post Traumatic Stress Disorder Schlenger (PS) scales of the Minnesota Multiphasic Personality Inventory-2 (MMPI) are valid meausres of other than male combat veterans. While the MMPI-2 appears to be consistent with the MMPI as a diagnostic indicator of PTSD among groups of Vietnam combat veterans, to date, no known research has been reported on the effectiveness of the PK or the PS scales of the MMPI-2 with other populations which report symptoms of PTSD (Graham, 1987).

Technical Approach:

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	13 Oct 94	**Protocol**	94-83	**Status:**	Ongoing
Title:	Impact of the Threat of War on Military Children.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): MAJ Nancy A. Ryan-Wenger			**Facility:** USA MEDDAC, FT Campbell, KY		
Department/Service: Nursing			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: The purpose of this study is to find out how well military children are handling this stressor in their lives and whether health professionals should be doing something more to help children deal with it. In a pilot study, several children have said that "no one has ever asked for my opinion before". This is an opportunity for the child to talk about this subject to someone who is objective and truly interested in what he or she has to say. Also, after completing the questionnaire, the child will become aware of the variety of coping strategies that he/she can use to deal with this and other life's stressors.

Technical Approach: There are questions about the child's thoughts and feelings, about worries and fears, and a few questions about what the child thinks or has heard about war. At any time during the interview that the child appears to be upset, the interview will be stopped. The interview will be tape-recorded so tht the interviewer can focus on the child and not extensive notetaking. ID numbers and not names will be used on all forms to protect the child's confidentiality.

Number of subjects enrolled: Eight.

Progress: Interviews not yet conducted. Research facilitator obtained subjects, then was deployed to Haiti. Recruitment and interviews will continue upon her return.

Problems Encountered: See above.

DETAIL SUMMARY SHEET

Date:	13 Feb 94	**Protocol**	94-46	**Status:**	Ongoing
Title:	Phase Ii of the HIV Seroconverter Risk Factor Study				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Jane Grimes, RN, MA			**Facility:** USA MEDDAC, FT Campbell, KY		
Department/Service: Preventive Medicine			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To evaluate biologic and behavioral determinants of HIV seroconversion by comparing medical, demographic, and behavioral histories of active duty personnel recently infected with HIV to histories of individuals who have not seroconverted over a similar time period.

Technical Approach: See HIV Protocol RV84

Number of subjects enrolled:

Progress: Study has not yet started.

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Mar 95	**Protocol**	95-14	**Status:**	Ongoing
Title:	Army Pregnancy Study, Relationships between a Female Soldier's Occupation and Birth Outcome.				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert J. Palowski, CPT, MC			**Facility:** Blanchfield Army Hospital FT Campbell, KY		
Department/Service: Preventive Medicine			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Continue		

Study Objective: To attempt to quantify risk or establish baseline rates for the offspring of female soldiers by CMF or MOS.

Technical Approach: The study is designed to follow soldiers and nonsoldiers prospectively over time to elucidate what the risk of adverse pregnancy outcomes to the offspring of female soldiers may be.

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Mar 95	**Protocol**	93-52	**Status:**	Completed
Title:	Pregnancy Exercise Patterns and Post-Partum Fitness				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Lori B. Newman, MAJ, AN			**Facility:** Blanchfield Army Hospital FT Campbell, KY		
Department/Service: OB/GYN			**Associate Investigators:** Terence J. Caldwell, LTC, AN Bari C. Knobel, MAJ, AN Judith L. Chantelois, MAJ, MC Frank W. Montgomery, III, Asst. Prof.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 95, Completed		

Study Objective: This study seeks to describe the existing exercise programs and postpartum fitness levels of 50 pregnant soldiers. It will use the Army Physical Fitness Test score and body fat measurements before and after pregnancy to compare self-reported exercise activity during pregnancy. The study will not alter individual's level of activity.

Technical Approach: Subjects will suppply the exercise data and PT scores with no disciplinary risk. Data on the delivery outcomes will also be collected.

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

DETAIL SUMMARY SHEET

Date:	9 Mar 95	**Protocol**	93-60	**Status:**	Completed
Title:	Clinical Comparability of Two Once-Daily Forms of Diltiazem: Effect of Substitution on Blood-Pressure Control				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Myron Piziak, LTC, MC		**Facility:** Lyster Army Hospital FT Rucker, AL			
Department/Service: Pharmacy		**Associate Investigators:** John Grabenstein, EdM, MS Roger P. Potyk, LTC(P), PharmD, MS			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 95, Completed			

Study Objective: To assess the comparability of clinical effects of Cardizem CD and Dilacor XR in the treatment of hypertension. The FDA has already found evidence of the safety and efficacy of these two dosage forms for this indication.

Technical Approach: See protocol plan.

Number of Subjects Enrolled to Date:

Progress:

Problems Encountered:

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